NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: March 2022

This bulletin includes details of the following new and updated NICE guidance – click on the titles below for further details:

1. **COVID-19 rapid guideline: managing COVID-19 NG191 (UPDATE)**
2. **Tagraxofusp for treating blastic plasmacytoid dendritic cell neoplasm *(terminated appraisal)* TA782**
3. **Sotorasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer TA781**
4. **Nivolumab with ipilimumab for untreated advanced renal cell carcinoma TA780**
5. **Dostarlimab for previously treated advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency TA779**
6. **Pegcetacoplan for treating paroxysmal nocturnal haemoglobinuria TA778**
7. **Solriamfetol for treating excessive daytime sleepiness caused by obstructive sleep apnoea TA777**
8. **Pitolisant hydrochloride for treating excessive daytime sleepiness caused by obstructive sleep apnoea TA776**
9. **Dapagliflozin for treating chronic kidney disease TA775**
10. **Lenalidomide for relapsed or refractory mantle cell lymphoma *(terminated appraisal)* TA774**
11. **Empagliflozin for treating chronic heart failure with reduced ejection fraction TA773**
12. **Atidarsagene autotemcel for treating metachromatic leukodystrophy (MLD) HST18**
13. **Hypertension in adults: diagnosis and management (UPDATE) NG136**
14. **Mental wellbeing at work NG212**
15. **Type 2 diabetes in adults: management (UPDATE) NG28**
16. **Diabetes (type 1 and type 2) in children and young people: diagnosis and management (UPDATE) NG18**
17. **Type 1 diabetes in adults: diagnosis and management (UPDATE) NG17**
18. **Otitis media (acute): antimicrobial prescribing (UPDATE) NG91**
19. **Integrated health and social care for people experiencing homelessness NG214**
20. **Disabled children and young people up to 25 with severe complex needs: integrated service delivery and organisation across health, social care and education NG213**

21. **Liposuction for chronic lipoedema IPG721**
22. **Percutaneous insertion of a cystic duct stent after cholecystostomy for acute calculous cholecystitis IPG720**
23. **Endoscopic balloon dilation for subglottic or tracheal stenosis IPG719**
24. **Intramedullary distraction for lower limb lengthening IPG718**
25. **Endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach IPG717**
26. **UroShield for preventing catheter-associated urinary tract infections MTG69**
27. **myCOPD for managing chronic obstructive pulmonary disease MTG68**
28. **Prontosan for treating acute and chronic wounds MTG67**
29. **3C Patch for treating diabetic foot ulcers MTG66**
30. **Freelite assays for diagnosing multiple myeloma and related conditions *(terminated assessment)* DG47**
31. **Joint replacement (primary): hip, knee and shoulder QS206**
32. **Neonatal parenteral nutrition QS205**
33. **Fetal alcohol spectrum disorder QS204**
34. **Diabetes in children and young people (UPDATE) QS125**
35. **Current NICE Consultations**

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.

March 2022: NICE added a new recommendation on awake prone positioning and updated existing recommendations on non-invasive respiratory support. NICE also updated existing recommendations on casirivimab and imdevimab - for people hospitalised because of COVID-19.

Technology Appraisals (TAs)

Tagraxofusp for treating blastic plasmacytoid dendritic cell neoplasm *(terminated appraisal)* TA782

NICE is **unable to make a recommendation** on tagraxofusp for treating blastic plasmacytoid dendritic cell neoplasm. This is because the company did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Sotorasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer TA781

Recommendations

Sotorasib is **recommended** for use within the **Cancer Drugs Fund** as an option for treating KRAS G12C mutation-positive locally advanced or metastatic non-small-cell lung cancer in adults whose disease has progressed on, or who cannot tolerate, platinum-based chemotherapy or anti-PD-1/PD-L1 immunotherapy. It is recommended only if the conditions in the managed access agreement for sotorasib are followed.

This recommendation is not intended to affect treatment with sotorasib 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

Lung cancer is the third most common cancer and the most common cause of cancer death in the UK. The majority of lung cancers are diagnosed at an advanced stage, when the cancer has spread to lymph nodes and other organs in the chest (locally advanced disease; stage III) or to other parts of the body (metastatic disease; stage IV). Up to 85% of lung cancers are non-small-cell lung cancers (NSCLC). NSCLC may be grouped by tumour histology into squamous cell carcinoma, adenocarcinoma and large-cell carcinoma, with the latter 2 being collectively referred to as 'non-squamous' lung cancer.

KRAS is a protein that controls a signalling pathway crucial for cell growth, differentiation and survival. KRAS is the most frequently mutated oncogene in cancer, including lung cancer.

The aims of treatment for advanced NSCLC are to prolong survival and improve quality of life. Currently, treatment choices are influenced by the presence of biological markers, histology (squamous or non-squamous) and prior treatments. There are currently no treatments available that target KRAS G12C.

Sotorasib is a small molecule inhibitor of KRAS G12C protein, which locks it in an inactive state. This may block signalling between tumour cells and stop further growth. Sotorasib is given as an oral tablet.

Financial Factors

This technology is commissioned by NHS England.

It is estimated that around 850 people per year in England with KRAS G12C mutation-positive locally advanced or metastatic NSCLC are eligible for treatment with sotorasib.

Sotorasib 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 sotorasib available to the NHS at a reduced cost.

The resource impact of sotorasib will be covered by the Cancer Drugs Fund budget. More evidence on sotorasib is being collected. Once further follow-up data from CodeBreaK100 trial and direct comparative data with docetaxel from the CodeBreaK200 trial are available, NICE will decide whether or not to recommend it for use on the NHS and update the guidance. It will be available through the Cancer Drugs Fund until then.

Nivolumab with ipilimumab for untreated advanced renal cell carcinoma TA780

This guidance updates and replaces NICE TA581 (published May 2019). This technology was originally available through the Cancer Drugs Fund.

Recommendations

Nivolumab with ipilimumab is **recommended**, within its marketing authorisation, as an option for untreated advanced renal cell carcinoma in adults:

- whose disease is intermediate or poor risk as defined in the International Metastatic Renal Cell Carcinoma Database Consortium criteria and
- only if the company provides nivolumab with ipilimumab according to the commercial arrangement.

The Technology

Renal cell carcinoma (RCC) is a cancer that usually originates in the lining of the tubules of the kidney (the smallest tubes inside the nephrons) that help filter the blood and make urine. RCC is the most common type of kidney cancer. There are several types of RCC. The main ones are clear cell, papillary and chromophobe.

Metastatic RCC, in which the tumour has spread beyond the regional lymph nodes to other parts of the body, is defined as stage IV. Early small RCC tumours are usually asymptomatic; the diagnosis of early RCC is often incidental after abdominal scans for other reasons. The most common presenting symptoms of advanced RCC are blood in the urine, a palpable mass in the flank or abdomen and abdominal pain. Other non-specific symptoms include fever, night sweats, malaise and weight loss.

Localised radical approaches including nephron-sparing surgery, radical nephrectomy and ablative therapies may be curative in people with localised tumours. The aim of treatment is to prevent the growth and survival of cancer cells within the tumour

In untreated RCC, NICE TA169 recommends sunitinib as a first-line treatment option for people with advanced and/or metastatic renal cell carcinoma. NICE TA215 recommends pazopanib as a first-line treatment option for people with advanced renal cell carcinoma who have not received prior cytokine therapy.

Nivolumab a fully humanised IgG4 monoclonal antibody which targets and blocks the programmed cell death-1 receptor (PD-1), to promote an anti-tumour immune response. It is administered intravenously. Ipilimumab is a recombinant human anti CTLA-4 monoclonal antibody which blocks the effects of CTLA-4 to enhance T-cell mediated immune responses to tumour cells. It is administered intravenously.

Financial Factors

This technology is commissioned by NHS England.

Additional evidence collected as part of the Cancer Drugs Fund managed access agreement shows that nivolumab with ipilimumab improves how long people live compared with sunitinib. Sunitinib and pazopanib are considered to be similarly effective.

NICE state that the most likely cost-effectiveness estimates for nivolumab with ipilimumab are within the range that NICE usually considers an acceptable use of NHS resources.

NICE estimate that in Devon, 43 patients will receive treatment treatment with nivolumab with ipilimumab. This is based on the current number of people receiving treatment through the Cancer Drug Fund (25% of the eligible population). This number is expected to remain constant over 5 years.

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

Dostarlimab for previously treated advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency TA779

Recommendations

Dostarlimab is **recommended** for use within the **Cancer Drugs Fund** as an option for treating advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency in adults who have had platinum-based chemotherapy. It is recommended only if the conditions in the managed access agreement are followed.

This recommendation is not intended to affect treatment with dostarlimab 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

Endometrial cancer is a cancer of the lining of the uterus, known as the endometrium. It is the most common type of uterine cancer. When diagnosed, endometrial cancer is categorised between stage 1 and 4, depending on the size of the cancer and how far it has spread. Advanced (stage 3 or 4) endometrial cancer is when the cancer has spread outside the uterus. Recurrent endometrial cancer is when the cancer returns after primary treatment. The cancer can recur anywhere. The symptoms of recurrence are variable but include abdominal pain, bloating, nausea, shortness of breath, vaginal bleeding and changes in bowel or bladder habits.

In normal cells, the mismatch repair (MMR) system recognises and repairs genetic mismatches generated during DNA replication. Around 26% of endometrial tumours have a defect in the MMR system, meaning unstable and dysfunctional DNA is not degraded. Tumours with MMR deficiency can develop microsatellite instability, which is a change in the length of repetitive sequences in tumour DNA compared with normal DNA. Tumours with high microsatellite instability may upregulate immune checkpoints, including programmed cell death protein (PD-1) and programmed cell death ligand 1 (PD-L1).

The first treatment for endometrial cancer is usually removal of the uterus, fallopian tubes and ovaries.

In advanced endometrial cancer, debulking surgery may be carried out to remove as much of the cancer as possible, and platinum-based chemotherapy can be added on to the surgery. Radiotherapy may be used for people who cannot have surgery, or alongside surgery.

Dostarlimab is a humanised monoclonal antibody, which works by attaching to the PD-1 protein on the surface of cancer cells. This helps the immune system to recognise and attack the cancer by preventing the inhibition of T-cell mediated immune responses. It is administered intravenously.

Financial Factors

This technology is commissioned by NHS England.

NICE estimate that in England around 280 adults per year with advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency who have had platinum-based chemotherapy are eligible for treatment with dostarlimab.

Dostarlimab 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 dostarlimab available to the NHS at a reduced cost.

The resource impact of dostarlimab will be covered by the Cancer Drugs Fund budget. More evidence on dostarlimab is being collected until the final results of the GARNET trial are available. After this, NICE will decide whether or not to recommend it for use on the NHS and update the guidance.

Pegcetacoplan for treating paroxysmal nocturnal haemoglobinuria TA778

Recommendations

Pegcetacoplan is **recommended**, within its marketing authorisation, as an option for treating paroxysmal nocturnal haemoglobinuria (PNH) in adults who have anaemia after at least 3 months of treatment with a C5 inhibitor. It is recommended only if the company provides pegcetacoplan according to the commercial arrangement.

The Technology

Paroxysmal nocturnal haemoglobinuria (PNH) is a rare blood condition in which red blood cells are attacked by the body's immune system. It is characterised by intravascular haemolysis (rupturing of red blood cells) with resultant anaemia often leading to transfusion dependence, severe disabling symptoms of haemolysis and, frequently, thrombosis (blood clotting).

PNH is an acquired chronic condition that is associated with complications that can be severely debilitating and life threatening including abdominal pain, kidney problems, fatigue, shortness of breath, bleeding and blood clots, dysphagia, organ damage and premature mortality.

Although there is currently no NICE technology appraisal guidance on treating PNH, NHS England commissions the C5 complement inhibitor eculizumab. Allogeneic stem cell transplantation may be curative but is associated with significant risks and is only considered for patients with severe bone marrow failure. Other interventions, notably red blood cell transfusions, folic acid, iron tablets and anti-coagulant treatments are offered to prevent or treat complications.

Pegcetacoplan is a is a PEGylated cyclic peptide inhibitor of complement C3 that prevents the complement-mediated destruction of red blood cells. It is administered by subcutaneous injection.

Financial Factors

This technology is commissioned by NHS England.

NICE do not expect this guidance to have a significant impact on resources. This is because the technology is a further treatment option and the overall cost of treatment for this patient group is unlikely to change significantly with the introduction of pegcetacoplan.

For adults with anaemia while having a C5 inhibitor, pegcetacoplan is more effective and costs less than ravulizumab and eculizumab.

The company has a commercial arrangement, this makes pegcetacoplan available to the NHS with a discount.

Solriamfetol for treating excessive daytime sleepiness caused by obstructive sleep apnoea TA777

Recommendations

Solriamfetol is **not recommended**, within its marketing authorisation, to improve wakefulness and reduce excessive daytime sleepiness in adults with obstructive sleep apnoea whose sleepiness has not been satisfactorily treated by primary obstructive sleep apnoea therapy, such as continuous positive airway pressure (CPAP).

This recommendation is not intended to affect treatment with solriamfetol 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

Excessive daytime sleepiness (EDS), also known as hypersomnia, means people struggle to stay awake and alert during the day (or equivalent waking hours), leading to an irrepressible need to sleep or unintended lapses into drowsiness or sleep. One cause of excessive sleepiness is obstructive sleep apnoea (OSA).

OSA is a condition in which a person stops breathing for a short time when they are asleep because of a closing or narrowing of the throat. The blocking of the airway leads to breathing difficulties which causes people to wake suddenly and subsequently interrupts sleep. Interruption of normal sleeping patterns leads to excessive daytime sleepiness, and reduced concentration and alertness. OSA is associated with neuropsychological impairment, metabolic and cardiovascular co-morbidities and increased mortality.

Current clinical practice for treating excessive sleepiness caused by OSA is to treat the underlying condition. Managing OSA may involve lifestyle changes such as losing weight, stopping smoking and limiting alcohol consumption. Continuous positive airway pressure (CPAP) is recommended as a treatment option for adults with moderate or severe symptomatic OSA, and for adults with mild OSA who have symptoms that affect their daily activities and have not responded to lifestyle

changes (NICE TA139). Other treatment options for OSA include mandibular advancement devices and surgery.

Solriamfetol is a phenylalanine-derived, second-generation wake-promoting agent. Solriamfetol prevents the reuptake of dopamine and noradrenaline and indirectly enhances dopaminergic and noradrenergic neurotransmission. It is administered orally.

Financial Factors

CCGs are the responsible commissioner for this technology.

NICE state that the cost-effectiveness estimates for solriamfetol compared with standard care alone are uncertain. They are also likely to be higher than what NICE normally considers an acceptable use of NHS resources.

Pitolisant hydrochloride for treating excessive daytime sleepiness caused by obstructive sleep apnoea TA776

Recommendations

Pitolisant hydrochloride is **not recommended**, within its marketing authorisation, to improve wakefulness and reduce excessive daytime sleepiness in adults with obstructive sleep apnoea whose sleepiness has not been satisfactorily treated by primary obstructive sleep apnoea therapy such as continuous positive airway pressure (CPAP), or who cannot tolerate it.

This recommendation is not intended to affect treatment with pitolisant hydrochloride 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

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as a treatment option for adults with moderate or severe symptomatic OSA, and for adults with mild OSA who have symptoms that affect their daily activities and have not responded to lifestyle changes (NICE TA139). Other treatment options for OSA include mandibular advancement devices and surgery.

Pitolisant hydrochloride binds to the histamine H3 receptor, which activates histamine-releasing neurons in the brain and increases wakefulness. It is administered orally.

Financial Factors

CCGs are the responsible commissioner for this technology.

NICE have stated that due to uncertainty with the clinical evidence and economic model, the cost-effectiveness estimates are also uncertain. They are also likely to be higher than what NICE normally considers an acceptable use of NHS resources.

Dapagliflozin for treating chronic kidney disease TA775

Recommendations

Dapagliflozin is **recommended** as an option for treating chronic kidney disease (CKD) in adults. It is recommended only if:

- it is an add-on to optimised standard care including the highest tolerated licensed dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs), unless these are contraindicated, and
- people have an estimated glomerular filtration rate (eGFR) of 25 ml/min/1.73 m^2 to 75 ml/min/1.73 m^2 at the start of treatment and:
    - have type 2 diabetes or
    - have a urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more.

This recommendation is not intended to affect treatment with dapagliflozin 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

Chronic kidney disease (CKD) is a condition where the kidneys do not work as well as they should and it is linked with adverse outcomes including cardiovascular disease. People with CKD do not usually have symptoms during the early stages of the disease but symptoms including weight loss and poor appetite, swollen ankles, feet or hands, shortness of breath, tiredness, feeling sick and blood in the urine can develop as the disease progresses.

The severity of CKD is determined by the estimated glomerular filtration rate (eGFR), with 6 categories ranging from normal to kidney failure, and the albumin to creatinine ratio (ACR), with 3 categories (normal to mild increase, moderate increase and severe increase).

An ACR of more than 3 mg/mmol (a moderate or severe increase) is an indicator for albuminuria, when albumin, a protein that is normally found in the blood, is found in the urine. CKD can progress to kidney failure in a small but significant percentage of people, which may require dialysis or a kidney transplant.

Treatment aims to prevent or delay progression of CKD, reduce or prevent complications, and reduce the risk of cardiovascular disease. NICE have produced a clinical guideline on chronic kidney disease in adults (CG182)

Dapagliflozin is a sodium-glucose co-transporter 2 (SGLT-2) inhibitor. The mechanism of action in CKD is not yet fully understood. It is administered orally.

Financial Factors

This technology is commissioned by CCGs.

NICE state that for the groups for which there is good enough clinical evidence, the cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources.

NICE estimate that in Devon, the prevalence of CKD is 39,992 people. Of these, 7,519 people will be eligible for treatment with dapagliflozin. Current cost of practice in Devon is approximately £451,000. It is anticipated that the cost of practice at year five will be approximately £745,000, this is an increased resource impact of approximately £294,000. This is a Secondary Care impact only.

Lenalidomide for relapsed or refractory mantle cell lymphoma *(terminated appraisal)* TA774

NICE is **unable to make a recommendation** on lenalidomide (Revlimid) for treating relapsed or refractory mantle cell lymphoma. This is because the company did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Empagliflozin for treating chronic heart failure with reduced ejection fraction TA773

Recommendations

Empagliflozin is **recommended** as an option for treating symptomatic chronic heart failure with reduced ejection fraction in adults, only if it is used as an add-on to optimised standard care with:

- an angiotensin-converting enzyme (ACE) inhibitor or angiotensin 2 receptor blocker (ARB), with a beta blocker and, if tolerated, a mineralocorticoid receptor antagonist (MRA), or
- sacubitril valsartan with a beta blocker and, if tolerated, an MRA.

Start empagliflozin for treating symptomatic heart failure with reduced ejection fraction on the advice of a heart failure specialist. Monitoring should be done by the most appropriate healthcare professional.

This recommendation is not intended to affect treatment with empagliflozin that was started in the NHS before this guidance was published. People having treatment outside these recommendations 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

Heart failure is a complex clinical syndrome of signs and symptoms, generally defined as the inability of the heart to supply sufficient blood flow to meet the body's needs. It is caused by structural or functional abnormalities of the heart, commonly resulting from coronary artery disease. Other conditions that can increase the risk of heart failure include; ischemic heart disease, atrial fibrillation, valve disease, hypertension, diabetes, chronic obstructive pulmonary disease, and asthma.

Heart failure may be associated with left ventricular systolic dysfunction (that is, reduced left ventricular ejection fraction, where the left pumping chamber's ability to pump is impaired) but may also be associated with reduced ejection fraction, defined as an ejection fraction below 40%

NICE CG106 for chronic heart failure in adults recommends offering an angiotensin-converting enzyme (ACE) inhibitor and a beta-blocker for people with heart failure with reduced ejection fraction. If ACE inhibitors are contraindicated or not tolerated, an angiotensin receptor blocker (ARB) should be considered. A mineralocorticoid receptor antagonist (MRA) in addition to an ACE inhibitor (or ARB) and beta-blocker should be offered if symptoms continue.

TA388 recommends sacubitril valsartan as an option for treating symptomatic chronic heart failure with reduced ejection fraction

TA267 recommends ivabradine in combination with standard therapy.

TA679 recommends dapagliflozin as an option for treating symptomatic chronic heart failure with reduced ejection fraction in adults, only if it is used as an add-on to optimised standard care.

Empagliflozin is a sodium-glucose cotransporter 2 (SGLT-2) inhibitor. The mechanism of action of empagliflozin in heart failure with reduced ejection fraction is not yet fully understood. It is administered orally.

Financial Factors

This technology is commissioned by CCGs.

NICE do not expect this guidance to have a significant impact on resources. This is because the technology is a further treatment option and the overall cost of treatment will be similar.

Evidence from a clinical trial shows that empagliflozin plus standard care reduces the risk of dying from cardiovascular causes compared with placebo plus standard care. It also shows that it reduces the likelihood of hospitalisation for heart failure. There are no trials directly comparing empagliflozin with the most appropriate comparator, dapagliflozin. However, an indirect comparison suggests that empagliflozin is likely to be similar to dapagliflozin in reducing the risk of dying and the likelihood of hospitalisations for heart failure.

Highly Specialised Technology Guidance (HSTs)

Atidarsagene autotemcel for treating metachromatic leukodystrophy (MLD) HST18

Recommendations

Atidarsagene autotemcel is **recommended**, within its marketing authorisation, as an option for treating metachromatic leukodystrophy with mutations in the arylsulphatase A (ARSA) gene:

- for children who have late infantile or early juvenile types, with no clinical signs or symptoms
- for children who have the early juvenile type, with early clinical signs or symptoms, and who can still walk independently and have no cognitive decline.

It is recommended only if the company provides atidarsagene autotemcel according to the commercial arrangement.

Atidarsagene autotemcel should be delivered in a highly specialised service by a specialist multidisciplinary team.

The Technology

Metachromatic leukodystrophy (MLD) is an autosomal recessive genetic disorder, caused by a deficiency in the enzyme arylsulphatase A (ARSA). This deficiency causes sulphatides to accumulate, producing microglial damage, progressive demyelination and neurodegeneration, leading to neurological problems. MLD is a progressive and chronically disabling condition, which substantially reduces quality of life and life expectancy.

There are 3 main types based on genotype and age of symptom onset:

- The late infantile (LI). It is the most common and most aggressive form and usually starts before 30 months. Symptoms include peripheral neuropathy, muscle weakness, sight and hearing loss, difficulty walking, loss of speech, cognitive decline, and seizures. The

condition progresses rapidly so that children lose awareness of their surroundings over a few years. Death normally occurs within 5 to 8 years.

- The juvenile type. Symptoms include impaired fine motor skills and concentration, behavioural problems, difficulties with movement, slurred speech, incontinence and seizures. Initial disease progression is slower than with the LI type but symptoms can progress rapidly. Death normally occurs within 10 to 20 years. It can be subdivided into:
    - early juvenile (EJ) disease, starting between 30 months and 6 years
    - late juvenile disease, starting between 7 and 16 years.
- The adult type is the rarest form and usually starts after 16 years. Symptoms include a decline in school or work performance, cognitive decline, personality changes and memory lapses. The decline can be slow and almost imperceptible. Death normally occurs within 25 years.

MLD is managed in the NHS by neurodisability and metabolic consultants at regional centres, who advise local hospital and community-based teams.

Atidarsagene autotemcel is a gene therapy medicinal product that expresses the human arylsulphatase A (ARSA) gene. When successfully engrafted, the genetically modified cells secrete functional ARSA enzyme, which is absorbed by surrounding cells and used to break down or prevent build-up of harmful sulphatides. The effects of atidarsagene autotemcel are potentially lifelong. Atidarsagene autotemcel is administered as a single-dose intravenous infusion.

Financial Factors

This technology is commissioned by NHS England.

Clinical evidence suggests that the gene therapy atidarsagene autotemcel improves mobility and cognitive function and could correct the enzyme deficiency caused by the condition.

The cost-effectiveness estimates show that atidarsagene autotemcel provides substantial extra health and quality-of-life benefits. But how much is uncertain, and it varies for the different types of the condition. Taking into account the long-term uncertainty, for children with late infantile and early juvenile forms of the condition, the cost-effectiveness estimates are within what NICE normally considers an acceptable use of NHS resources for highly specialised technologies.

NICE Guidelines (NGs)

Hypertension in adults: diagnosis and management (UPDATE) NG136

This guideline covers identifying and treating primary hypertension (high blood pressure) in people aged 18 and over, including people with type 2 diabetes. It aims to reduce the risk of cardiovascular problems such as heart attacks and strokes by helping healthcare professionals to diagnose hypertension accurately and treat it effectively.

March 2022: NICE reviewed the evidence and made a new recommendation on blood pressure targets for people who have both hypertension and cardiovascular disease. NICE also reassessed evidence on antihypertensive drug treatment from the previous version of this guideline (without a new evidence review) and made a new recommendation to cover people who have both hypertension and cardiovascular disease.

Public Health Guidelines

Mental wellbeing at work NG212

This guideline updates and replaces NICE guideline PH22 (November 2009).

This guideline covers how to create the right conditions for mental wellbeing at work. It aims to promote a supportive and inclusive work environment, including training and support for managers and helping people who have or are at risk of poor mental health.

Type 2 diabetes in adults: management (UPDATE) NG28

This guideline covers care and management for adults (aged 18 and over) with type 2 diabetes. It focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.

March 2022: NICE have reviewed the evidence on continuous glucose monitoring (CGM) for adults with type 2 diabetes.

NICE have also made one change without an evidence review: in the section on self-monitoring of capillary blood glucose, the word 'capillary' has been added to the heading and recommendations, to make it clear that recommendations apply to adults who are using capillary blood glucose monitoring rather than CGM.

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (UPDATE) NG18

This guideline covers the diagnosis and management of type 1 and type 2 diabetes in children and young people aged under 18. The guideline recommends how to support children and young people and their families and carers to maintain tight control of blood glucose to reduce the long-term risks associated with diabetes.

March 2022: NICE have reviewed the evidence and made new recommendations on continuous glucose monitoring (CGM) for children and young people with type 1 diabetes.

NICE have also made one change without an evidence review: In the section on monitoring capillary blood glucose, wording has been added to the heading and recommendations to make it clear that recommendations apply to children and young people who are using capillary blood glucose monitoring rather than CGM.

Type 1 diabetes in adults: diagnosis and management (UPDATE) NG17

This guideline covers care and treatment for adults (aged 18 and over) with type 1 diabetes. It includes advice on diagnosis, education and support, blood glucose management, cardiovascular risk, and identifying and managing long-term complications.

March 2022: NICE have reviewed evidence on the diagnosis of type 1 diabetes and continuous glucose monitoring (CGM).

NICE have also made some changes without an evidence review: In the first diagnosis recommendation, the term 'diagnosis' has been changed to 'initial diagnosis' to differentiate between this and later recommendations on revisiting the initial diagnosis.

Antimicrobial Prescribing Guidelines

Otitis media (acute): antimicrobial prescribing (UPDATE) NG91

This guideline sets out an antimicrobial prescribing strategy for acute otitis media (ear infection). It aims to limit antibiotic use and reduce antimicrobial resistance. Acute otitis media can be caused by viruses or bacteria. It lasts for about a week, and most children get better in 3 days without antibiotics. Serious complications are rare.

March 2022: NICE added a new recommendation on eardrops containing an anaesthetic and an analgesic because a licensed preparation is now available in the UK. They moved recommendations on non-antimicrobial treatments earlier in the guideline.

Social Care Guidelines

Integrated health and social care for people experiencing homelessness NG214

This guideline covers providing integrated health and social care services for people experiencing homelessness. It aims to improve access to and engagement with health and social care, and ensure care is coordinated across different services.

Disabled children and young people up to 25 with severe complex needs: integrated service delivery and organisation across health, social care and education NG213

This guideline covers support for disabled children and young people with severe complex needs, from birth to 25 years. It aims to encourage education, health and social care services to work together and provide more coordinated support to children and young people, and their families and carers.

Interventional Procedures Guidance (IPGs)

Liposuction for chronic lipoedema IPG721

Recommendations

Evidence on the safety of liposuction for chronic lipoedema is inadequate but raises concerns of major adverse events such as fluid imbalance, fat embolism, deep vein thrombosis, and toxicity from local anaesthetic agents. Evidence on the efficacy is also inadequate, based mainly on retrospective studies with methodological limitations. Therefore, this procedure should **only be used in the context of research**.

Further research should report:

- patient selection, including age, effects of hormonal changes (which should include effects seen during puberty and menopause) and the severity and site of disease
- details of the number and duration of procedures, the liposuction technique used (including the type of anaesthesia and fluid balance during the procedure), and any procedure-related complications
- long-term outcomes, including weight and body mass index changes
- patient-reported outcomes, including quality of life.

Patient selection should be done by a multidisciplinary team, including clinicians with expertise in managing lipoedema.

The procedure should only be done in specialist centres by surgeons experienced in this procedure.

The Condition

Lipoedema is characterised by an abnormal, usually symmetrical, accumulation of fat in the legs, hips, buttocks, and occasionally arms. It is a different condition from obesity and from lymphoedema. The aetiology of lipoedema is unknown, but hormonal changes, weight gain and genetics are each thought to be involved. Lipoedema is considerably more prevalent in women and very rarely affects men. Symptoms include swollen, heavy legs that are painful to touch and bruise easily. Feet do not usually have fat accumulation. The size and shape of legs, and the resultant mobility issues and pain, can have a profoundly negative effect on quality of life, and physical and mental health.

Treatment typically involves healthy lifestyle changes, conservative therapy and, in severe cases, surgery. The fat associated with lipoedema is usually resistant to diet modification and exercise. Conservative therapy, including compression and manual lymphatic drainage is sometimes used to treat lipoedema, but is ineffective at removing abnormal fat. The main surgical treatment for lipoedema is liposuction. In people who also have obesity, there is emerging evidence that

bariatric surgery may help reduce fat from both lipoedema-affected and unaffected areas of the body.

The Procedure

The aim of liposuction for lipoedema is to reduce limb bulk, reduce pain, and to improve mobility and functioning. Liposuction for chronic lipoedema can be done under general or local anaesthesia. Several small incisions are made in the limb.

Liposuction for chronic lipoedema usually involves infiltrating the limb with large volumes of fluid (tumescence) to allow the cannula to glide through the tissue with minimal damage to blood vessels and lymphatics. Liposuction can also be done using a tourniquet with no or minimal initial fluid infiltration.

Tumescent liposuction needs an infiltration pump to deliver the tumescent fluid. Cannulas, connected to a vacuum pump, are then inserted into the incisions and oedematous adipose tissue is removed by vacuum aspiration. In tumescent liposuction, both fat and tumescent fluid are suctioned out together.

Using vibrating cannulas (power-assisted liposuction) or water-jet-assisted liposuction can help remove fat more easily. Water-jet-assisted liposuction needs less initial infiltration because fluid is simultaneously infiltrated and aspirated during liposuction.

The procedure can take 1 to 4 hours depending on the size of the treatment area. Immediately after liposuction, a compression bandage is applied to the limb to control any bleeding and to prevent postoperative oedema.

Percutaneous insertion of a cystic duct stent after cholecystostomy for acute calculous cholecystitis IPG720

Recommendations

Evidence on the safety and efficacy of percutaneous insertion of a cystic duct stent after cholecystostomy for acute calculous cholecystitis is inadequate in quality and quantity. But because patients would otherwise need permanent external drainage, the procedure can be considered for this condition, as long as **special arrangements** for clinical governance, consent, and audit or research are in place.

Clinicians wanting to do percutaneous insertion of a cystic duct stent after cholecystostomy for acute calculous cholecystitis should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.

- Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.
- Regularly review data on outcomes and safety for this procedure.

Patient selection should be done by a multidisciplinary team.

This procedure should only be done in specialist centres by clinicians with specific training and experience in this procedure.

Further research should report details of patient selection, the procedure undertaken, the type of stent used and whether the patient is later able to have definitive surgery.

The Condition

Acute calculous cholecystitis is inflammation of the gallbladder caused by a gallstone or biliary sludge that blocks the cystic duct. The blockage in the cystic duct causes bile to build up in the gallbladder, increasing the pressure inside it and causing it to become inflamed. Symptoms include pain, fever, nausea and vomiting.

Treatments include intravenous fluids, medicines (analgesics and antibiotics), endoscopic or percutaneous biliary drainage, and surgery (laparoscopic or open cholecystectomy). NICE's guideline on gallstone disease (CG188) recommends offering early laparoscopic cholecystectomy (to be carried out within 1 week of diagnosis) to patients with acute cholecystitis.

The Procedure

This procedure places a stent via a cholecystostomy tract into the cystic duct to provide antegrade gallbladder drainage and prevent further obstructive episodes of cholecystitis. This procedure is suitable for patients who otherwise need long-term external drainage.

Before the procedure, a percutaneous cholecystostomy and drainage is done to resolve the acute episode. This procedure is usually done using conscious sedation. The cholecystostomy drain is used for cholangiography to confirm cystic duct obstruction. Under fluoroscopic guidance, a guidewire and catheter are passed through the cholecystostomy tract, through the cystic duct and into the duodenum. A stent is then inserted and placed in or across the cystic duct.

After the procedure, an external gallbladder drain is usually left in situ for a few days to ensure that there is good antegrade drainage of bile into the duodenum. The external drain can then be removed after a satisfactory cholangiogram.

Endoscopic balloon dilation for subglottic or tracheal stenosis IPG719

This guidance replaces IPG425 (published April 2012)

Recommendations

Evidence on the safety of endoscopic balloon dilation for subglottic or tracheal stenosis is adequate. The most serious complication related to the procedure, independent of age, is tracheal laceration but this is well recognised.

- For babies, children, and young people, evidence on the efficacy of the procedure is adequate to support using it, provided that **standard arrangements** are in place for clinical governance, consent and audit.
- For adults, evidence on the efficacy of the procedure is limited. So, it should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wanting to do endoscopic balloon dilation for subglottic or tracheal stenosis in adults should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.
- Regularly review data on outcomes and safety for this procedure.

This procedure should only be done in specialist centres by clinicians trained in the technique, and with anaesthesia and intensive care support.

Report any problems with a medical device using the Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme.

The Condition

Subglottic or tracheal stenosis is a narrowing of the airway. It can be congenital, traumatic or, most commonly, iatrogenic after prolonged endotracheal intubation. Symptoms include hoarseness, stridor, exercise intolerance and respiratory distress. In severe cases complete obstruction may happen, needing continued intubation or tracheostomy.

Treatment options include inhaled or oral steroids to treat inflammation and reduce the severity of stenosis. A cricoid-split operation can decompress the subglottis and prevent development of stenosis in babies. For people with severe and established stenosis, endoscopic techniques such as stent insertion or laser ablation are used. Alternatively, open surgical repair is done to increase the diameter of the stenosed segment with a graft or stent (expansion surgery) or to remove the stenotic area (resection surgery).

The Procedure

The aim of endoscopic balloon dilation is to dilate airway strictures with minimal mucosal trauma by applying pressure to an area of stenosis. The procedure is most commonly done on iatrogenic stenoses, which are typically soft. It is less commonly done on harder, established stenoses.

The procedure is usually done under general anaesthesia, using direct laryngoscopic or bronchoscopic visualisation. A balloon device is introduced into the airway and the balloon is gently inflated, applying radial pressure circumferentially to the stricture. After dilation, the balloon is deflated and the device is withdrawn. The procedure may be used in combination with other treatments. It can be repeated if needed. The aim is to widen the stenotic airway and improve symptoms.

Intramedullary distraction for lower limb lengthening IPG718

This guidance replaces IPG197 (published December 2006)

Recommendations

Evidence on the safety and efficacy of intramedullary distraction for lower limb lengthening is limited in quantity and quality. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research. This guidance is not intended to cover this procedure for bilateral lower limb lengthening for people with short stature.

Clinicians wanting to do intramedullary distraction for lower limb lengthening should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers as appropriate) clear information to support shared decision making, including NICE's information for the public.

- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.
- Regularly review data on outcomes and safety for this procedure.

Patient selection should be done by a multidisciplinary team that ideally includes physiotherapy and psychological support.

This technically challenging procedure should only be done in specialist centres by surgeons with training and specific experience in limb lengthening techniques.

Report any problems with a medical device using the Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme.

Further research should report details of patient selection, device selection, procedural outcomes, long-term outcomes including quality of life, the need for repeat interventions or surgery, and complication rates. This research could be registry data.

The Condition

People may have different limb lengths because of trauma or infection (acquired) or, because of hypoplasia or dysplasia of the femur or tibial (congenital). Unequal leg length can cause a limp, limit functional ability and have effect on other joints.

Lengthening of an abnormally short lower limb can be done after an osteotomy using an external fixation device. This exerts force along the long axis of the bone to induce new bone formation (distraction osteogenesis). The main problems with external fixation include infection of the pin tracts, and external frames that are impractical and aesthetically unacceptable. Once the external fixation is removed, in some people with underlying bone pathology, new bone is augmented by either an internal plate fixation or an intramedullary nail.

The Procedure

Once inserted and fixed, intramedullary distraction systems can be lengthened over time using different techniques. The aim is to lengthen the bone in a controlled manner.

With this procedure, under general anaesthesia, an osteotomy is done while avoiding damage to the periosteum and its blood supply. The adjustable intramedullary nail-like device is then implanted into the intramedullary space. Its proximal and distal sections are fixed to the relevant section of the bone with sterile locking screws. It then exerts a force along the long axis of the bone, which stimulates new bone formation (distraction osteogenesis) in the gap, causing bone lengthening. Over days, weeks or months, sequential distractions are used to produce the target limb length.

Different devices achieve distraction in different ways.

Soon after the procedure, with help from the physiotherapy team, people are able to partially weight bear. After clinical assessment, and when there is radiological evidence of adequate bone consolidation across the gap, full weight bearing is possible. The intramedullary device is usually removed after about 2 years using standard surgical techniques.

Endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach IPG717

Recommendations

Evidence on the safety and efficacy of endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach is inadequate in quality and quantity. Therefore, this procedure should only be used in the **context of research**.

Further research should ideally be randomised controlled trials or registry studies. It should report patient selection, tumour type, size and anatomical position, and long-term outcomes (such as tumour recurrence).

Patient selection should be done by a multidisciplinary team.

This procedure should only be done in specialist centres by interventional upper gastrointestinal endoscopists with specific training in this procedure.

The Condition

Gastrointestinal stromal tumours are a type of soft tissue sarcoma formed from abnormal cells in the tissues of the gastrointestinal tract. Gastrointestinal stromal tumours are most common in the stomach and small intestine but they can develop anywhere along the length of the gastrointestinal tract.

The grade of gastrointestinal stromal tumour is based on the mitotic rate. There are 2 grades: G1 (low grade – the cancer cells have a low mitotic rate, they are growing slowly and less likely to spread) and G2 (high grade – the cancer cells have a high mitotic rate, they are growing faster and more likely to spread).

The choice of treatment for gastrointestinal stromal tumours depends on several factors, including the location, size and mitotic rate of the tumour, whether the tumour is metastatic, recurrent or refractory, and the person's overall health. The standard treatments include surgery (open,

laparoscopic, robotic or endoscopic surgery), targeted therapy using drugs or other substances, watchful waiting and supportive care.

The Procedure

This procedure uses a full thickness resection device, which allows endoscopic resection with a single step, clip and cut technique. For example, 1 device comprises a modified snare to remove the tumour and deeper layers of the stomach wall, and a clasp device that closes the full thickness of the stomach wall.

The device is attached to the end of an endoscope and advanced through the mouth and the oesophagus to the stomach. Gradual dilation may be needed to help the device pass through the upper and lower oesophageal sphincters. The tumour is grasped at its centre and slowly pulled into the cap of the device completely. A clip is released, closing the site of a potential defect in the stomach wall. A snare simultaneously encloses the tumour and cuts it away, then it is retrieved for histological analysis.

After the tumour is removed, the endoscope is reinserted and the surgical site is examined for signs of haemorrhage and to check that the clip has closed the stomach wall. The procedure is usually done with the patient under sedation, but sometimes general anaesthesia is needed.

Medical Technologies Guidance (MTGs)

UroShield for preventing catheter-associated urinary tract infections MTG69

Recommendations

More research is recommended on UroShield for preventing catheter-associated urinary tract infections (CAUTIs). It has potential to provide significant patient and healthcare system benefits but uncertainties in the evidence need to be addressed.

Research should be comparative, and it should address uncertainties about the effectiveness of UroShield in preventing catheter-associated UTIs and other catheter-related complaints such as blockages.

The Technology

A urinary catheter is used to empty the bladder and collect urine in a drainage bag. Indwelling catheters remain in place for many days or weeks and are held in position by an inflated balloon in the bladder. Some people may use catheters for their lifetime. An indwelling catheter can either be inserted through the urethra (indwelling urethral catheter) or through a small cut or incision in the lower part of abdomen (indwelling suprapubic catheter). Indwelling catheters may be used short term (usually up to around 14 days) or long term (weeks).

Around half of people who have long-term catheters experience problems such as pain, tissue damage, decreased mobility and hospital attendances associated with blockage. Nearly everyone with a catheter develops bacteria in their urine (bacteriuria) during the catheterisation period.

Catheter-associated urinary tract infection (CAUTI) is defined as the presence of symptoms or signs compatible with a UTI in people with a catheter with no other identified source of infection plus significant levels of bacteria in a catheter or a midstream urine specimen when the catheter has been removed within the previous 48 hours.

Urinary tract infection is an important cause of morbidity and mortality in the healthcare setting, accounting for 19% of all hospital-acquired infections. Of these, it is estimated that between 43% and 56% are CAUTI. The NICE guideline on healthcare-associated infections (CG139) states that the risk of blockages, encrustations and catheter-associated infections in long-term urinary catheters should be minimised through patient-specific regimens such as reviewing the frequency of planned catheter changes, increasing fluid intake and documenting catheter blockages.

UroShield is an ultrasound device designed to reduce the risk of CAUTI by reducing bacterial colonisation and biofilm formation on indwelling urinary catheters. The technology works by generating low-intensity 90 kHz ultrasonic surface acoustic waves, which propagate throughout the catheter's length on its inner and outer lumens. The company claims these acoustic waves prevent bacteria attaching and forming a biofilm and also reduce friction between the catheter and the person's internal tissues. It claims this reduces the pain, discomfort, and spasm associated with indwelling urinary catheters.

Financial Factors

CCGs are the responsible commissioner for this technology.

Cost analyses suggest that UroShield may be cost saving in hospital and in people with repeated UTIs or catheter blockages in community care. But because the clinical effectiveness of UroShield is uncertain and the published evidence very limited, the cost savings are also uncertain. Therefore, more research recommended.

myCOPD for managing chronic obstructive pulmonary disease MTG68

Recommendations

More research is recommended on myCOPD for managing chronic obstructive pulmonary disease (COPD) in adults. Using it for self-managing COPD and remote pulmonary rehabilitation could provide significant patient and healthcare system benefits if uncertainties in the evidence are addressed.

Research should compare myCOPD with standard care for:

- people who use it to self-manage COPD
- people who are referred for pulmonary rehabilitation.

The Technology

Chronic Obstructive Pulmonary Disease (COPD) is a long-term respiratory condition. It is the second most common lung disease in the UK after asthma. Most people are not diagnosed until they are 50 years of age or older. It is more common in men than in women.

Typical COPD symptoms include breathlessness when active, a persistent cough and frequent chest infections. Without treatment, the symptoms are likely to gradually get worse. Some patients may periodically experience sudden and acute worsening of symptoms knowns as exacerbations which may be triggered by infection. Optimal treatment can help control symptoms, slow the progression of the disease and prevent exacerbations, but the condition is not curable.

The majority of people with COPD live at home and their management is likely to be shared between healthcare professionals in primary and secondary care. Most people with mild and moderate symptoms and those who are not experiencing frequent exacerbations will be managed predominately in primary care. People with severe COPD are likely to have frequent exacerbations leading to hospital admissions.

The NICE guideline NG115 provides recommendations on the management of stable COPD covering smoking cession, inhaled therapy, oral therapy, oxygen therapy, pulmonary rehabilitation and managing pulmonary hypertension.

myCOPD is a digital tool for people with chronic obstructive pulmonary disease (COPD) and healthcare professionals. It is intended to support people to manage COPD. It can be used by people with any stage of COPD. Functions within the myCOPD app include:

- education on how to use inhalers correctly
- a self-management plan to help people understand what medicine to take and when
- a prescription assessment function to cross-check prescribed medicine, and identify any conflicts
- a COPD assessment for people to track their symptoms and learn how to control them
- access to an online 6-week pulmonary rehabilitation course including an incremental exercise programme and education sessions to help promote self-management.

Clinicians can review the person's data to remotely monitor their symptoms and if appropriate suggest a change to their medicines. These suggestions are automatically shared with the person through the app.

Financial Factors

CCGs are the responsible commissioner for this technology.

NICE state that cost savings are uncertain because of limitations in the clinical evidence. There is also a lack of information about how much myCOPD affects healthcare resource use, such as

unscheduled hospital appointments. More evidence is needed to resolve these uncertainties, therefore further research is recommended.

The company provides an unlimited licence plan to healthcare organisations such as CCGs who want to make the technology available across their regions. Based on a 3-year contract, this unlimited licence plan has an annual cost of £0.25 per person registered with a GP in the region. Alternatively, pulmonary rehabilitation service providers who do not have regional access to the technology can obtain an unlimited licence plan at a cost of £10,000 per year.

Prontosan for treating acute and chronic wounds MTG67

Recommendations

More research is recommended on Prontosan for treating chronic wounds. There is some evidence that it is clinically effective but not enough to recommend it for routine use. Prontosan is **not recommended** for treating acute wounds because the evidence is very limited.

Research should be a randomised controlled trial on the effectiveness of Prontosan compared with saline or water in chronic wounds of different types. Wounds should be followed up until completely healed, and time to healing should be measured.

The Technology

Prontosan is intended for use in acute and chronic wounds only when they require cleansing. The types of wounds that may be encountered include:

- Acute non-infected and infected wounds such as trauma wounds (skin lacerations, bites, cuts or crush injuries) and post-operative wounds.
- Chronic non-infected and infected wounds including pressure ulcers, leg ulcers and diabetic foot ulcers.
- Thermal, chemical and post-radiation wounds including burns.

It is estimated that in the UK, over 2 million people per year have wounds that require treatment. A cohort analysis of 1,000 NHS patients that have wounds suggested that about 39% of wounds do not heal within the first year and may need additional therapy.

Current treatment options for cleansing acute and chronic wounds include sterile saline or water. Care of acute or chronic non-healing wounds aims to improve wound condition, promote healing and minimise the risk of further complications. If the wound is suspected of being infected, a microbiological sample is usually taken and an antibiotic prescribed to treat the organism causing the infection.

Prontosan is a range of topical solutions and gels used for cleansing, rinsing and moistening acute and chronic wounds. Prontosan includes, Prontosan Wound Irrigation Solution, Prontosan Wound Gel and Prontosan Wound Gel X (extra thick gel)

The solution and gels contain an antimicrobial polyhexanide and a betaine surfactant. Prontosan is the only wound cleansing solution or gel that contains these 2 active ingredients. The company claims they work together to prevent biofilm forming in the wound bed and break it down if it has formed. The company claims that it cleanses and removes slough, devitalised tissue and other wound debris.

Prontosan is intended for cleansing, rinsing or moistening acute and chronic wounds. It can be used by healthcare professionals in community and acute care settings, such as outpatient clinics, hospital inpatient care, GP surgeries, postoperative care and at the patient's home. The company states that brief training may be needed, but this is likely to be unnecessary for staff who are already trained in cleansing wounds with saline or water.

Financial Factors

CCGs are the responsible commissioner for this technology.

Most of the evidence about Prontosan's effectiveness is not of good quality. It may speed up wound healing and reduce infections compared with saline in chronic wounds, but more evidence is needed to confirm this. There is very little evidence about using Prontosan for treating acute wounds.

NICE state that cost analyses suggest that Prontosan is cost saving compared with saline in chronic wounds. But there is not enough good quality evidence about its clinical effectiveness, which limits how reliable the cost analysis is. More research is recommended to address the uncertainties.

3C Patch for treating diabetic foot ulcers MTG66

Recommendations

3C Patch is **not recommended** as a cost-saving option for diabetic foot ulcers.

The Technology

The 3C Patch is intended to treat hard-to-heal diabetic foot ulcers that have not responded to standard wound care. Hard-to-heal diabetic foot ulcers are often considered as those that have not shown substantial healing (reduction in size by 50% or more) after 4 weeks of treatment.

It is estimated that more than 3.9 million people are living with a diagnosis of diabetes in the UK. Foot complications such as diabetic foot ulcers are common in people with diabetes.

Foot problems in people with diabetes have a significant financial impact on the NHS. A study published in 2019 reported that during 2014 to 2015, between £837 million and £962 million was spent on managing foot ulcers or undertaking amputations in people with diabetes in England, representing 0.8% to 0.9% of the country's NHS budget. Ulceration equated to 90% of expenditure.

The aims of treatment for diabetic foot ulcers are to dress and protect the ulcer, to prevent or treat any infection and to promote healing. NICE's guideline on the prevention and management of diabetic foot problems (NG19) recommends that diabetic foot ulcers are assessed by a healthcare professional and that one or more of the following is offered to people as standard care for treating diabetic foot ulcers:

- Offloading
- Control of foot infection
- Control of ischaemia
- Wound debridement
- Wound dressings

3C Patch is a single-use medical device that is used as part of wound care for foot ulcers in people with diabetes. 3C Patch is used in combination with the 3CP centrifuge. Together the device and the centrifuge are referred to as the 3C Patch system.

The system is used to make an individual, biological patch from a person's own blood. The patch is a disc-shaped layered matrix of fibrin, leukocytes and platelets and acts as a concentrated source of cells, growth factors and signalling molecules, which are thought to promote wound healing.

To make the patch, blood is drawn directly into the 3C Patch device, and then spun for about 20 minutes in the 3CP centrifuge. The centrifuge has optical sensors and uses an automatic prespecified programme that performs all the steps needed to create the patch. The patch is applied directly to the ulcer and kept in place with a non-adhesive primary dressing. A separate secondary dressing can also be used to manage exudate.

Financial Factors

CCGs are the responsible commissioner for this technology.

NICE state that the clinical evidence on ulcers that are not healing shows that using 3C Patch led to more ulcers healing at 20 weeks and faster ulcer healing. However, there were uncertainties around whether the evidence would generalise to current NHS practice because of how and when the treatment would be used. Cost analysis also showed that the clinical benefits seen in the trial are unlikely to lead to cost savings in practice.

Diagnostic Guidance (DGs)

Freelite assays for diagnosing multiple myeloma and related conditions *(terminated assessment)* DG47

NICE **no longer plan to develop guidance** on Freelite assays for diagnosing multiple myeloma and related conditions in primary care. NICE will review this decision if a stakeholder notifies NICE again of the topic.

NICE Quality Standards

Joint replacement (primary): hip, knee and shoulder QS206

This quality standard covers care for adults before, during and after primary elective hip, knee or shoulder joint replacement. It describes high-quality care in priority areas for improvement. It does not cover joint replacement as treatment for primary or secondary cancer affecting the bones.

Neonatal parenteral nutrition QS205

This quality standard covers parenteral nutrition (intravenous feeding) for babies born preterm, up to 28 days after their due birth date, and babies born at term, up to 28 days after their birth. It describes high-quality care in priority areas for improvement.

Fetal alcohol spectrum disorder QS204

This quality standard covers assessing and diagnosing fetal alcohol spectrum disorder (FASD) in children and young people. It also covers support during pregnancy to prevent FASD. It describes high-quality care in priority areas for improvement.

Diabetes in children and young people (UPDATE) QS125

This quality standard covers diagnosing and managing type 1 and type 2 diabetes in children and young people (under 18). It describes high-quality care in priority areas for improvement.

March 2022: Changes have been made to align this quality standard with the updated NG18. Statement 4 has been updated to reflect changes to the guidance on continuous glucose monitoring for type 1 diabetes. Links, definitions, data sources and source guidance sections have also been updated throughout.

Current NICE Consultations

Title / link	End date of consultation
Imlifidase for preventing kidney transplant rejection in people with chronic kidney disease [ID1672]	01/04/22
Teduglutide for treating short bowel syndrome [ID3937]	01/04/22
Diabetes in pregnancy (update)	08/04/22
Indoor air quality at home	11/04/22
Hip fracture: management	11/04/22
GID-MT563 NPi-200 for pupillary light reflex in critical care patients	11/04/22
Nivolumab with platinum- and fluoropyrimidine-based chemotherapy for untreated HER2-negative advanced gastric, gastro-oesophageal junction or oesophageal adenocarcinoma [ID1465]	13/04/22
Diabetes (type 1 and type 2) in children and young people: diagnosis and management - medicines for type 2 diabetes (update)	14/04/22
Artificial intelligence (AI) software to help clinical decision making in stroke	14/04/22
PLGF-based testing to help diagnose suspected preterm pre-eclampsia (update of DG23)	19/04/22
Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides [ID3831]	19/04/22
Alpelisib in combination with fulvestrant for treating advanced hormone-receptor positive, HER2-negative, PIK3CA-mutated breast cancer [ID3929]	21/04/22
Removal, preservation and subsequent re-implantation of ovarian tissue to prevent symptoms from the menopause	25/04/22
Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia	25/04/22
Tunnelled peritoneal drainage catheter insertion for refractory ascites in cirrhosis	25/04/22
Type 2 diabetes in adults: management - periodontal disease	27/04/22
Type 1 diabetes in adults: diagnosis and management – periodontal disease	27/04/22
Diabetes (type 1 and type 2) in children and young people: diagnosis and management – periodontal disease	27/04/22

Produced by the Clinical Effectiveness Team, NHS Devon CCG for distribution
D-CCG.ClinicalEffectiveness@nhs.net