NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: June 2020

Hyperlinks to the relevant NICE web page are included below.

NICE rapid COVID-19 guidelines

NICE has published a further rapid guideline on the care of people with suspected and confirmed COVID-19, and in patients without COVID-19.

These guidelines have been developed to maximise patient safety whilst making the best use of NHS resources and protecting staff from infection using the interim process and methods for developing rapid guidelines on COVID-19 and based on evidence and expert opinion.

COVID 19 rapid guideline: renal transplantation NG178

This guideline covers children, young people and adults who need or who have had a kidney transplant, and people who are donating a kidney (live donors). It also advises transplant and referring centres on how to run their services, while keeping them safe for patients, donors and staff during the COVID-19 pandemic. Kidney transplants improve life expectancy and quality of life, and cost less than dialysis in the long term, so providing effective and safe services will benefit patients and make the best use of resources.

Technology Appraisals (TAs)

Ranibizumab for treating diabetic retinopathy TA637 (terminated appraisal)

NICE is **unable to make a recommendation** about the use in the NHS of ranibizumab (Lucentis) for treating diabetic retinopathy because Novartis did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Eculizumab for treating refractory myasthenia gravis TA636 (terminated appraisal)

NICE is **unable to make a recommendation** on eculizumab (Soliris) for treating refractory myasthenia gravis because Alexion Pharma UK did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Ramucirumab with erlotinib for untreated EGFR-positive metastatic non-small-cell lung cancer TA635 (terminated appraisal)

NICE is **unable to make a recommendation** on ramucirumab (Cyramza) with erlotinib for untreated epidermal growth factor receptor (EGFR)-positive metastatic non-small-cell lung cancer, because Eli Lilly and Company Limited did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Daratumumab with lenalidomide and dexamethasone for untreated multiple myeloma TA634 (terminated appraisal)

NICE is **unable to make a recommendation** on daratumumab (Darzalex) with lenalidomide and dexamethasone for untreated multiple myeloma, because Janssen did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Avatrombopag for treating thrombocytopenia in people with chronic liver disease needing a planned invasive procedure TA626

Recommendations

Avatrombopag is **recommended**, within its marketing authorisation, as an option for treating severe thrombocytopenia (that is, a platelet count of below 50,000 platelets per microlitre of blood) in adults with chronic liver disease having a planned invasive procedure.

The technology

Avatrombopag has a marketing authorisation for the treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure.

The recommended dosage of avatrombopag is based on the patient's platelet count:

- below 40,000 platelets per microlitre of blood – 60 mg once daily
- 40,000 to below 50,000 platelets per microlitre of blood – 40 mg once daily.

Avatrombopag is taken orally. Dosing should begin 10 to 13 days before the planned procedure and patients should have their procedure 5 to 8 days after the last dose of avatrombopag.

Financial factors

This technology is commissioned by CCGs.

NICE does not expect this guidance to have a significant impact on resources because the technology is a further treatment option and due to this the overall incremental cost of treatment is not deemed to be significant.

The addition of avatrombopag in the treatment pathway may help reduce the need for platelet transfusions. It may also help increase the time in which procedures can be scheduled and reduce hospital stays.

Note: The scope for this multiple technology appraisal included both avatrombopag and lusutrombopag. However, because of a delay in getting an agreed list price for

avatrombopag, this topic was split into 2 separate appraisals. Please see NICE technology appraisal guidance 617 for recommendations on lusutrombopag.

Ustekinumab for treating moderately to severely active ulcerative colitis TA633

Recommendations

Ustekinumab is **recommended** as an option for treating moderately to severely active ulcerative colitis in adults when conventional therapy or a biological agent cannot be tolerated, or the disease has responded inadequately or lost response to treatment, only if:

- a tumour necrosis factor-alpha inhibitor has failed (that is the disease has responded inadequately or has lost response to treatment) or
- a tumour necrosis factor-alpha inhibitor cannot be tolerated or is not suitable, and
- the company provides ustekinumab at the same price or lower than that agreed with the Commercials Medicines Unit.

This recommendation is not intended to affect treatment with ustekinumab 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

Ustekinumab has a marketing authorisation that includes the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

Induction treatment is administered intravenously as a weight-based dose using 130 mg concentrate for solution for infusion. Maintenance treatment is administered as a subcutaneous injection using solution for injection in a vial or pre-filled syringe.

Financial factors

This technology is commissioned by CCGs.

NICE does not expect this guidance to have a significant impact on resources because the technology is a further treatment option and the overall cost of treatment will be comparable to the current treatment options available.

This treatment option is only available to patients when other treatment has failed (the disease has responded inadequately or has lost response to treatment), or they have not been able to tolerate or are otherwise inappropriate for a TNF-alpha inhibitor.

The list price of ustekinumab is £2,147 per 130-mg vial of concentrate for solution for infusion, and £2,147 per 90-mg solution for injection in a pre-filled syringe (excluding VAT; BNF online). The annual treatment costs are £14,482 in the induction year, and £9,304 per year for maintenance treatment (year 2 onwards). However the company has agreed a nationally available price reduction for ustekinumab with the Commercial Medicines Unit which is commercial in confidence.

Trastuzumab emtansine for adjuvant treatment of HER2-positive early breast cancer TA632

Recommendations

Trastuzumab emtansine is **recommended**, within its marketing authorisation, as an option for the adjuvant treatment of human epidermal growth factor receptor 2 (HER2)-positive early breast cancer in adults who have residual invasive disease in the breast or lymph nodes after neoadjuvant taxane-based and HER2-targeted therapy. It is recommended only if the company provides trastuzumab emtansine according to the commercial arrangement.

The technology

Trastuzumab emtansine, as a single agent, is indicated for the adjuvant treatment of adult patients with HER2-positive early breast cancer who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2-targeted therapy. Trastuzumab emtansine is administered by IV infusion.

Financial factors

This technology is commissioned by NHS England.

Populating the NICE resource template for Devon, it is estimated that 18 people with HER2 positive breast cancer are eligible for treatment with trastuzumab emtansine. 16 people will have trastuzumab emtansine from year 2 onwards once uptake has reached 90%.

Trastuzumab emtansine costs £1,641.01 per 100-mg vial and £2,625.62 per 160-mg vial (powder for solution for infusion; excluding VAT; BNF online). However the company has a commercial arrangement which makes trastuzumab emtansine available to the NHS with a discount. The size of the discount is commercial in confidence.

Fremanezumab for preventing migraine TA631

Recommendations

Fremanezumab is **recommended** as an option for preventing migraine in adults, only if:

- the migraine is chronic, that is, 15 or more headache days a month for more than 3 months with at least 8 of those having features of migraine
- at least 3 preventive drug treatments have failed and
- the company provides it according to the commercial arrangement.

Stop fremanezumab if the migraine frequency does not reduce by at least 30% after 12 weeks of treatment.

This recommendation is not intended to affect treatment with fremanezumab 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

Fremanezumab is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month. Fremanezumab is administered as a subcutaneous injection with 2 dosing options: 225 mg once a month or 675 mg every 3 months (quarterly). The treatment benefit should be assessed within 3 months after starting treatment. Any decision to continue treatment should be taken on an individual patient basis. Evaluating the need to continue treatment is recommended regularly afterwards.

Financial factors

This technology is commissioned by CCGs.

Populating the NICE resource template for Devon, it is estimated that 1,295 people with chronic migraine in Devon are eligible for treatment with fremanezumab. It is estimated that 29 people will receive 12 weeks of fremanezumab in each year, and 117 people will continue to have fremanezumab from year 2024/25 onwards once market share has reached 20%.

The price of fremanezumab is £450.00 per 225-mg injection (BNF online). However the company has a commercial arrangement which makes fremanezumab available to the NHS with a commercial in confidence discount.

NICE notes that fremanezumab offers an alternative to botulinum toxin type A. Where people choose fremanezumab instead of botulinum toxin A, there is potential to free up clinic capacity. This is because people whose migraine is responding to botulinum toxin A have 4 treatments per year (per TA260); people whose migraine is responding to fremanezumab may need two clinic attendances per year. The reduction in clinic appointments depends on how long people remain on treatment. There is no reduction in appointments where people were previously receiving best supportive care.

Botulinum toxin A treatment requires a 30-minute hospital appointment every 12 weeks for administration (TA260). Fremanezumab requires a single monthly injection or 3 injections every quarter, all of which can be self-administered. Training may be required before a person can self-administer the treatment.

Highly specialised technology guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Intravenous fluid therapy in children and young people in hospital NG29 (update)

This guideline covers general principles for managing intravenous (IV) fluids for children and young people under 16 years, including assessing fluid and electrolyte status and prescribing IV fluid therapy. It applies to a range of conditions and different settings.

In June 2020, NICE amended a recommendation to clarify the use of isotonic crystalloids for routine maintenance in term neonates.

Joint replacement (primary): hip, knee and shoulder NG157

This guideline covers care before, during and after a planned knee, hip or shoulder replacement. It includes recommendations to ensure that people are given full information about their options for surgery, including anaesthesia. It offers advice for healthcare professionals on surgical procedures and ensuring safety during operations. It also offers guidance on providing support and rehabilitation before and after surgery.

This guideline includes recommendations on:

- information and shared decision making for people having joint replacements
- preoperative rehabilitation
- anaesthesia
- tranexamic acid to minimise blood loss
- preventing infections and avoiding implant selection errors
- procedures for knee, hip and shoulder replacement
- postoperative rehabilitation and long-term care

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)

Intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention IPG673

Recommendations

Evidence on the safety and efficacy of intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention is limited in quantity and quality. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wishing to do intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention should:

- Inform the clinical governance leads in their NHS trusts.
- Give patients clear information to support shared decision making, including NICE's information for the public.
- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these.
- Enter details about all patients having intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention onto the National Institute for Cardiovascular Outcomes Research (NICOR) database, and review local clinical outcomes.

The procedure should only be done by an experienced interventional cardiologist with specific training in the procedure.

Research could be a randomised controlled trial, comparing the procedure with current standard therapies, or an observational cohort study, including using registry data. Studies should include details of patient selection, the size and shape of the lesion, procedural success, minimal stent area and longer-term outcomes including survival.

The condition

Coronary artery calcification (intimal and medial calcifications) increases the complexity of percutaneous treatment strategies in coronary interventions. It contributes to arterial wall stiffness, suboptimal stent delivery and expansion, in-stent restenosis, high rates of stent thrombosis and the need for subsequent target lesion revascularisation after endovascular interventions.

Standard endovascular treatment options for modifying calcification or plaques during percutaneous coronary intervention (PCI) include: balloon angioplasty using standard or super high-pressure non-compliant balloons; cutting or scoring balloons; and stenting with or without coronary atherectomy (such as excisional, rotational, orbital or laser atherectomy). The aim with these treatments is to allow optimal stent expansion and achieve maximal luminal gain. However, they may sometimes lead to localised wall injury, balloon rupture, or the risk of coronary vessel dissections or perforation.

The procedure

Shockwave intravascular lithotripsy is administered to the calcified coronary artery before stent deployment during PCI.

A percutaneous guidewire is passed from the radial or femoral artery into a coronary artery. Then, an intravascular lithotripsy catheter with embedded emitters enclosed in an integrated angioplasty balloon is passed and connected to an external generator with a connector cable. The catheter is advanced to the target lesion guided by radiopaque markers on the catheter. The balloon is then inflated with a saline and contrast solution to ensure contact with the vessel wall. The lithotripsy cycle is then activated. For every cycle, the catheter emits localised, high-energy, pulsatile, unfocused, circumferential, acoustic, sonic, pressure waves (lasting microseconds).

These waves pass through the inflated balloon into the wall of the coronary artery. As the waves travel along the wall and the connective tissue, they disrupt calcium deposits (both intimal and medial calcium) by microfracturing the calcified lesions.

The cycle can be repeated until the lesion has been expanded sufficiently to allow optimal stent placement. Intravascular lithotripsy during PCI may improve stent delivery and expansion and modify focal intravascular calcium, while limiting localised injury to the endovascular surface.

Medical Technologies Guidance (MTGs)

Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia MTG49

Recommendations

Evidence **supports the case** for adopting Rezum for treating lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) in the NHS. Rezum relieves LUTS and improves quality of life.

Rezum is a minimally invasive procedure. It should be considered as a treatment option for people with:

- moderate to severe LUTS (International Prostate Symptoms Score [IPSS] typically 13 or over) and
- a moderately enlarged prostate (typically between 30 cm^3 and 80 cm^3).

Cost modelling estimates that Rezum is cost saving compared with standard treatments such as transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP) by more than £550 per person over 4 years. Savings compared with UroLift are uncertain. This is because of uncertainty about some of the assumptions in the cost modelling for that comparison.

The technology

Rezum is water vapour (steam) therapy for treating lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH). The technology uses water vapour to destroy excess prostate tissue with the aim of relieving symptoms.

The water vapour is injected into the prostate through a single-use device attached to a urological endoscope. The process is intended to disrupt cell membranes, leading to cell death and shrinking the prostate. The intention is to relieve obstructive symptoms without interfering with surrounding tissues that might impair sexual function.

The vapour is injected for 9 seconds during treatment. The number of times this has to be done in each lobe of the prostate depends on the length of the prostatic urethra. It can be customised to the configuration of the gland. A maximum number of 15 full injections can be done with each delivery device although fewer injections are needed for most treatments. The procedure is usually done in the NHS under general anaesthesia or local anaesthesia with sedation, and lasts up to 20 minutes.

Financial factors

This technology is commissioned by CCGs.

NICE does not expect this guidance to have a significant impact on resources. As a result of this guidance there is expected to be a small switch to Rezum from current surgical procedure methods. The largest switch is expected to be from transurethral resection of the prostrate (TURP) and Urolift to Rezum.

For providers of surgical treatments, the cost of the device and consumables of Rezum is higher when compared to the existing surgical treatment option of TURP. The cost of capital is included as part of the consumable costs for Rezum.

If a provider switches from TURP to Rezum the additional device and consumable costs are estimated to be £1,150 per procedure, however, if the switch is from Urolift to Rezum there is an estimated saving of £190 per procedure.

There is no expected change in tariff due to the switch to Rezum from other surgical methods. For providers, implementing this guidance is expected to generate a capacity benefit. This will arise from a reduction in revisions, shorter theatre times and a reduced length of stay when using Rezum.

Diagnostics Guidance (DGs)

Tests to help assess risk of acute kidney injury for people being considered for critical care admission (ARCHITECT and Alinity i Urine NGAL assays, BioPorto NGAL test and NephroCheck test) DG39

Recommendations

There is **not enough evidence to recommend** the routine use of the ARCHITECT and Alinity i Urine neutrophil gelatinase-associated lipocalin (NGAL) assays, BioPorto NGAL test or NephroCheck test to help assess the risk of acute kidney injury for people being considered for critical care admission.

Further research is recommended to assess:

- the clinical effectiveness of defined care bundles to prevent or reduce the effect of acute kidney injury in defined NHS patient populations who could benefit from preventive care for acute kidney injury
- the effect on clinical outcomes of having the tests to guide care to prevent acute kidney injury.

The tests

The NephroCheck test measures the level of 2 biomarkers (tissue inhibitor of metalloproteinase 2 [TIMP-2] and insulin-like growth factor binding protein 7 [IGFBP-7]) in urine and uses the concentrations to help assess risk of moderate to severe acute kidney injury in the subsequent 12 hours.

The ARCHITECT and Alinity i Urine NGAL assays are chemiluminescent microparticle immunoassays for the quantitative determination of NGAL in human urine.

The BioPorto NGAL test is a particle-enhanced turbidimetric immunoassay for the quantitative determination of NGAL in human urine, ethylenediaminetetraacetic acid (EDTA) plasma and heparin plasma.

NICE Quality Standards

Sepsis QS161 (update)

This quality standard covers the recognition, diagnosis and early management of sepsis for all populations. It describes high-quality care in priority areas for improvement.

In June 2020, NICE updated statement 2 to better reflect their guidance on clinical review for people with suspected sepsis in acute hospital settings.

Current NICE consultations

Title / link	End date of consultation
Acute coronary syndromes	01/07/2020
Tafamidis for treating transthyretin amyloid cardiomyopathy [ID1531]	02/07/2020
Caplacizumab for treating adults experiencing an episode of acquired thrombotic thrombocytopenic purpura [ID1185]	03/07/2020
SEM Scanner 200 for pressure ulcer prevention	10/07/2020
DHT pilot: Zio XT for detecting cardiac arrhythmias	10/07/2020
Testing strategies for Lynch syndrome in people with endometrial cancer	13/07/2020
Minimally invasive radical hysterectomy for early stage cervical cancer	23/07/2020
Swallowable gastric balloon capsule for weight loss	23/07/2020
Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver	23/07/2020
Minimally invasive radical hysterectomy for early stage cervical cancer	23/07/2020
Siponimod for treating secondary progressive multiple sclerosis [ID1304]	23/07/2020