NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: September 2019

Hyperlinks to the relevant NICE web page are included below.

Technology Appraisals (TAs)

Lenalidomide with bortezomib and dexamethasone for untreated multiple myeloma TA603 (terminated appraisal)

NICE is **unable to make a recommendation** on lenalidomide with bortezomib and dexamethasone for untreated multiple myeloma in adults because Celgene did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Pomalidomide with bortezomib and dexamethasone for treating relapsed or refractory multiple myeloma TA602 (terminated appraisal)

NICE is **unable to make a recommendation** on pomalidomide with bortezomib and dexamethasone for treating relapsed or refractory multiple myeloma in adults because Celgene did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Bezlotoxumab for preventing recurrent Clostridium difficile infection TA601 (terminated appraisal)

NICE is **unable to make a recommendation** on bezlotoxumab for preventing recurrent *Clostridium difficile* infection in adults because Merck Sharp & Dohme did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Pembrolizumab with carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer TA600

Recommendations

Pembrolizumab, with carboplatin and paclitaxel, is **recommended for use within the Cancer Drugs Fund** as an option for untreated metastatic squamous non-small-cell lung cancer (NSCLC) in adults only if:

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

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

The technology

Pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of metastatic squamous NSCLC in adults.

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

Financial factors

This technology is commissioned by NHS England.

NICE estimates that around 1,100 people per year are eligible for treatment with pembrolizumab. Pembrolizumab with carboplatin and paclitaxel will be available to the NHS in line with the managed access agreement with NHS England. The resource impact of pembrolizumab will be covered by the Cancer Drugs Fund budget.

As part of the managed access agreement, the technology will continue to be available through the Cancer Drugs Fund after the data collection period has ended and while the guidance is being reviewed. The aim of the review is to decide whether or not the drug can be recommended for routine use.

Sodium zirconium cyclosilicate for treating hyperkalaemia TA599

Recommendations

Sodium zirconium cyclosilicate is **recommended** as an option for treating hyperkalaemia in adults only if used:

- in emergency care for acute life-threatening hyperkalaemia alongside standard care or
- in outpatient care for people with persistent hyperkalaemia and chronic kidney disease stage 3b to 5 or heart failure, if they:
    - have a confirmed serum potassium level of at least 6.0 mmol/litre
    - are not taking an optimised dosage of renin-angiotensin-aldosterone system (RAAS) inhibitor because of hyperkalaemia and
    - are not on dialysis.

    Sodium zirconium cyclosilicate is recommended only if the company provides it according to the commercial arrangement.

In outpatient care, stop sodium zirconium cyclosilicate if RAAS inhibitors are no longer suitable.

This recommendation is not intended to affect treatment with sodium zirconium cyclosilicate 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

Sodium zirconium cyclosilicate has a marketing authorisation for the treatment of hyperkalaemia in adult patients.

The dosage in the marketing authorisation is:

Correction phase: The recommended starting dose of sodium zirconium cyclosilicate is 10g, administered 3 times a day orally as a suspension in water. When normal serum potassium levels are reached, the maintenance regimen should be followed. If normal serum potassium levels are not reached after 72 hours of treatment, sodium zirconium cyclosilicate should be stopped.

Maintenance phase: For people with normal serum potassium levels after the correction phase, the minimal effective dose of sodium zirconium cyclosilicate to prevent recurrence of hyperkalaemia should be established. A starting dose of 5g once daily is recommended, with possible titration up to a maximum of 10g once daily or down to 5g once every other day as needed to maintain a normal serum potassium level.

Financial factors

This technology is commissioned by CCGs.

NICE estimates that 13,600 people in England with hyperkalaemia are eligible for treatment with sodium zirconium cyclosilicate either in emergency care or outpatient care and 8,170 people will have sodium zirconium cyclosilicate (4,900 in emergency care and 3,270 outpatient care) from year 2023/24 onwards once uptake has reached 60% (36% emergency care and 24% outpatient care).

In Devon this equates to 295 people with hyperkalaemia eligible for treatment with sodium zirconium cyclosilicate, and 177 having treatment (106 in emergency care and 71 outpatient care) from year 2023/24.

The list price of sodium zirconium cyclosilicate has a discount that is commercial in confidence.

Benralizumab for treating severe eosinophilic asthma TA565 (update)

In September 2019 NICE removed a statement that benralizumab is not recommended if neither mepolizumab nor reslizumab is recommended. The statement was not needed because if asthma does not meet the criteria for using benzalizumab, then it also does not meet the criteria for using mepolizumab or reslizumab.

Recommendations

Benralizumab, as an add-on therapy, is recommended as an option for treating severe eosinophilic asthma that is inadequately controlled in adults despite maintenance therapy with high-dose inhaled corticosteroids and long-acting beta-agonists, only if:

- the person has agreed to and followed the optimised standard treatment plan and

- the blood eosinophil count has been recorded as 300 cells per microlitre or more and the person has had 4 or more exacerbations needing systemic corticosteroids in the previous 12 months, or has had continuous oral corticosteroids of at least the equivalent of prednisolone 5 mg per day over the previous 6 months (that is, the person is eligible for mepolizumab) or
- the blood eosinophil count has been recorded as 400 cells per microlitre or more with 3 or more exacerbations needing systemic corticosteroids in the past 12 months (that is, the person is eligible for reslizumab).

Benralizumab is recommended only if the company provides it according to the commercial arrangement.

If benralizumab, mepolizumab or reslizumab are equally suitable, start treatment with the least expensive option (taking into account drug and administration costs).

At 12 months:

- stop benralizumab if the asthma has not responded adequately or
- continue benralizumab if the asthma has responded adequately and assess response each year.

An adequate response is defined as:

  - a clinically meaningful reduction in the number of severe exacerbations needing systemic corticosteroids or
  - a clinically significant reduction in continuous oral-corticosteroid use while maintaining or improving asthma control.

These recommendations are not intended to affect treatment with benralizumab 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

Benralizumab is indicated as add-on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus long-acting beta-agonists.

The recommended dosage is 30mg every 4 weeks for the first 3 doses then every 8 weeks, given by subcutaneous injection using a pre-filled syringe.

Financial factors

This technology is commissioned by NHS England.

NICE estimates that 56,300 people in England with severe eosinophilic asthma are eligible for treatment with Benralizumab, and 2,300 people will have Benralizumab in year 5 once uptake has reaches 4%.

The list prices of benralizumab and the comparators mepolizumab and reslizumab have discounts that are commercial-in-confidence.

Highly specialised technology guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Abortion care NG140

This guideline covers care for women of any age (including girls and young women under 18) who request an abortion. It aims to improve the organisation of services and make them easier for women to access. Detailed recommendations on conducting abortions at different gestational stages are also included, to ensure that women get the safest and most effective care possible.

This guideline includes recommendations on:

- making it easier to access services
- reducing waiting times
- workforce and training
- choice of procedure
- expulsion at home for medical abortion up to and including 10^{+0} weeks
- cervical priming before surgical abortion
- improving access to contraception after an abortion

Twin and triplet pregnancy NG137

This guideline covers the care that should be offered to women with a twin or triplet pregnancy in addition to the routine care that is offered to all women during pregnancy. It aims to reduce the risk of complications and improve outcomes for women and their babies.

This guideline updates and replaces multiple pregnancy: antenatal care for twin and triplet pregnancies (NICE guideline CG129, September 2011). It also updates recommendations on multiple pregnancy in section 1.2.2 of NICE's guideline on caesarean section (CG132).

This guideline includes new and updated recommendations on:

- fetal complications
- screening and preventing preterm birth
- timing of birth
- mode of birth
- fetal monitoring during labour
- analgesia
- managing the third stage of labour

It also includes recommendations on:

- determining gestational age and chorionicity (the number of outer membranes that surround the babies)
- delivery of care, including specialist antenatal appointments
- general care
- maternal complications
- indications for referral to a tertiary level fetal medicine centre

Attention deficit hyperactivity disorder: diagnosis and management NG87 (update)

This guideline covers recognising, diagnosing and managing attention deficit hyperactivity disorder (ADHD) in children, young people and adults. It aims to improve recognition and diagnosis, as well as the quality of care and support for people with ADHD.

In September 2019, NICE amended the recommendation on assessment for people starting medication for ADHD to indicate that an ECG is not needed before starting stimulants, atomoxetine or guanfacine if cardiovascular history and examination are normal and the person is not on medicine that poses an increased cardiovascular risk.

Tuberculosis NG33 (update)

This guideline covers preventing, identifying and managing latent and active tuberculosis (TB) in children, young people and adults. It aims to improve ways of finding people who have TB in the community and recommends that everyone under 65 with latent TB should be treated. It describes how TB services should be organised, including the role of the TB control board.

In September 2019, NICE updated this guideline to reflect MHRA restrictions and precautions for the use of fluoroquinolone antibiotics following rare reports of disabling and potentially long-lasting or irreversible side effects.

Pneumonia in adults: diagnosis and management CG191 (update)

This guideline covers diagnosing and managing community- and hospital-acquired pneumonia in adults. It aims to improve accurate assessment and diagnosis of pneumonia to help guide antibiotic prescribing and ensure that people receive the right treatment.

In September 2019, NICE withdrew some recommendations on community-acquired pneumonia and hospital-acquired pneumonia because they have been replaced by recommendations in the NICE guidelines on pneumonia (community-acquired): antimicrobial prescribing and pneumonia (hospital-acquired): antimicrobial prescribing.

Head injury: assessment and early management CG176 (update)

This guideline covers the assessment and early management of head injury in children, young people and adults. It promotes effective clinical assessment so that people receive the right care for the severity of their head injury, including referral directly to specialist care if needed.

In September 2019, NICE updated the advice on when to have a CT scan to change warfarin to anticoagulants when investigating clinically important brain injuries.

Caesarean section CG132 (update)

This guideline covers when to offer caesarean section, procedural aspects of the operation and care after caesarean section. It aims to improve the consistency and quality of care for women who are considering a caesarean section or have had a caesarean section in the past and are now pregnant again.

In September 2019, NICE replaced the recommendations on caesarean section for women with a multiple pregnancy with links to the guideline on twin and triplet pregnancy.

Public Health Guidelines

None published this month.

Antimicrobial prescribing guidelines

Cellulitis and erysipelas: antimicrobial prescribing NG141

This guideline sets out an antimicrobial prescribing strategy for adults, young people, children and babies aged 72 hours and over with cellulitis and erysipelas. It aims to optimise antibiotic use and reduce antibiotic resistance.

This guideline includes recommendations on:

- treatment
- advice
- reassessment
- referral and seeking specialist advice
- choice of antibiotic

Pneumonia (hospital-acquired): antimicrobial prescribing NG139

This guideline sets out an antimicrobial prescribing strategy for adults, young people, children and babies aged 72 hours and over with a confirmed diagnosis of hospital-acquired pneumonia. It does not cover ventilator-associated pneumonia. It aims to optimise antibiotic use and reduce antibiotic resistance.

This guideline includes recommendations on:

- treatment
- reassessment and specialist advice
- choice of antibiotic

Pneumonia (community-acquired): antimicrobial prescribing NG138

This guideline sets out an antimicrobial prescribing strategy for adults, young people, children and babies aged 72 hours and over with a confirmed diagnosis of community-acquired pneumonia. It aims to optimise antibiotic use and reduce antibiotic resistance.

This guideline includes recommendations on:

- treatment
- advice
- reassessment
- referral and seeking specialist advice
- choice of antibiotic

Social Care guidelines

None published this month.

Interventional Procedures Guidance (IPGs)

Bioprosthetic plug insertion for anal fistula IPG662

Recommendations

Current evidence on the safety and efficacy of bioprosthetic plug insertion for anal fistula is adequate to support the use of this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit.

The procedure should only be done by a surgeon experienced in managing anal fistulas.

The condition

An anal fistula is an abnormal tract between the anal canal and the skin around the anus. It usually results from previous anal abscesses (cryptoglandular) and can be associated with other conditions such as inflammatory bowel disease and cancer. It may cause symptoms such as pain or discomfort in the anal area, and leakage of blood or pus. Anal fistulas can be classified according to their anatomical relationship with the external sphincter. Intersphincteric fistulas are the most common type and cross only the internal sphincter. Trans-sphincteric fistulas pass through the internal and external sphincter.

Treatment of anal fistulas commonly involves surgery. The type of surgery depends on the location and complexity of the fistula. For intersphincteric and low trans-sphincteric anal fistulas, the most common treatment is a fistulotomy or laying open of the fistula tract. For deeper fistulas that involve more muscle, and for recurrent fistulas,

a seton (a piece of suture material or rubber sling) may be used, either alone or with fistulotomy. Setons can be loose (designed to drain the sepsis but not for cure), or snug or tight (designed to cut through the muscles in a slow controlled fashion). Fistulas that cross the external sphincter at a high level are sometimes treated with a mucosal advancement flap or other procedures to close the internal opening. Other options for treating anal fistulas are to fill the tract with glue or paste.

The procedure

Bioprosthetic plug insertion for anal fistula aims to leave the sphincter muscles intact, allowing the use of subsequent treatments if needed.

The procedure is usually done using general anaesthesia. The fistula tract is identified using a probe or by imaging techniques, and it may be irrigated. A conical plug, usually made of porcine intestinal submucosa, is pulled into the tract until it blocks the internal opening. It is sutured in place at the internal opening. The external opening is not completely sealed so that drainage of the fistula can continue. The plug acts as a scaffold into which new tissue can grow.

High-intensity focused ultrasound for glaucoma IPG661

Recommendations

Evidence on the safety and efficacy of high-intensity focused ultrasound for glaucoma is inadequate in quality and quantity. Therefore, this procedure should only be used in the **context of research**.

Research should ideally take the form of randomised controlled trials comparing this procedure with standard therapies and should report safety events and long-term outcomes.

NICE may update the guidance on publication of further evidence.

The condition

Glaucoma is usually a chronic condition associated with elevated intraocular pressure. The most common type of glaucoma in the UK is primary open-angle glaucoma, also known as chronic open-angle glaucoma. It leads to progressive damage to the optic nerve. Early stages are usually asymptomatic but as the condition progresses it causes visual impairment and, if untreated, blindness.

NICE's guideline on glaucoma describes its diagnosis and management. Treatment is usually eye drops containing drugs that either reduce the production of aqueous humor (fluid) or increase its drainage. Surgical procedures such as trabeculectomy, drainage tubes, deep sclerectomy, viscocanalostomy or laser trabeculoplasty may also be used.

The procedure

This procedure uses high-intensity focused ultrasound (HIFU) to partially destroy the ciliary body to reduce the production of aqueous humor and thereby decrease the intraocular pressure.

The procedure can be done under regional, general or topical anaesthesia. One device available for this procedure consists of a compact operator console and a disposable probe (which includes a coupling cone and a therapy probe that generates the ultrasound beams). The coupling cone is placed directly on the centre of the patient's cornea and held in place by a low-vacuum suction ring. A ring-shaped therapy

probe (connected to the console) that generates ultrasound beams is inserted into the cone. The space between the eye, cone and the probe is filled with saline solution to ensure dissemination of ultrasound energy. By pressing the foot switch, miniature transducers in the ring-shaped probe are sequentially activated to deliver HIFU beams directly into the ciliary body. These beams pass through the scleral tissue without disruption of ocular tissue to reach the ciliary body. The ultrasound heats and inactivates tissue within the ciliary body to decrease the production of aqueous humor.

Implant insertion for prominent ears IPG660

Recommendations

Current evidence on the safety and efficacy of implant insertion for prominent ears is inadequate in quality and quantity. Therefore, this procedure should only be used in the **context of research**.

Further research should include comparisons of this procedure with current best therapy. It should address issues of patient selection, such as age and type of ear shape, nature of ear implants used, long-term efficacy and safety outcomes, and patient-reported outcomes using validated quality-of-life measures.

The condition

Protruding or prominent ears result when cartilaginous folds fail to form within the ear.

Surgery to correct protruding ears aims to reposition the elastic cartilage permanently while preserving a natural appearance. Cartilage-sparing techniques such as scoring, drilling and suturing of the cartilage may be used. Most techniques involve a post-auricular skin incision, although there has been a report of an incisionless otoplasty.

The procedure

This procedure is done under local anaesthesia. One or more implants are used to create or reshape the antihelical fold of the ear. The aim is to correct any ear prominence resulting from either poor definition or a lack of this fold.

The implant is inserted using an introducer and released onto the anterior surface of the cartilage, immediately reshaping it and correcting the ear prominence. The incision is closed using 1 or 2 dissolvable sutures, and the wound is then dressed with sterile tape. Typically, 1 implant is used in each ear, but more may be needed. The procedure usually takes about 20 minutes for both ears.

Medical Technologies Guidance (MTGs)

The 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites MTG25 (update)

In September 2019 NICE updated this guidance to reflect 2019 costs. The update also includes revised cost-saving estimates.

Recommendations

The case for adopting the 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites is supported by the evidence. This technology allows observation, and provides antiseptic coverage, of the catheter

insertion site. It reduces catheter-related bloodstream infections and local site infections compared with semipermeable transparent (standard) dressings. It can be used with existing care bundles.

The 3M Tegaderm CHG IV securement dressing should be considered for use in critically ill adults who need a central venous or arterial catheter in intensive care or high dependency units.

The estimated cost saving from using a 3M Tegaderm CHG IV securement dressing instead of a standard transparent semipermeable dressing is £93 per patient. This estimate is based on a baseline catheter-related bloodstream infection rate of 1.48 per 1,000 catheter days. Tegaderm CHG is estimated to be cost neutral when the baseline catheter-related bloodstream infection rate is 0.18 per 1,000 catheter days, and cost incurring when the baseline rate falls below that figure.

The technology

The 3M Tegaderm CHG IV securement dressing is a sterile transparent semipermeable polyurethane adhesive dressing with an integrated gel pad containing a 2% concentration by weight of chlorhexidine gluconate (CHG).

Tegaderm CHG is used to secure percutaneous devices and to cover and protect central venous and arterial catheter insertion sites. It aims to provide an effective barrier against external contamination. The dressing and the integrated gel pad are transparent to allow observation of the catheter insertion site. The integrated gel pad is designed to reduce skin and catheter colonisation in order to suppress regrowth of microorganisms commonly related to catheter-related bloodstream infections (CRBSI).

Financial factors

This technology is commissioned by CCGs.

In updated cost modelling, Tegaderm CHG is shown to be more cost-saving than was considered when the guidance was first issued.

NICE does not expect this amendment to the guidance to have a significant impact on resources as the potential savings from implementing the recommendations in England are expected to be less than £1 million per year (or £1,800 per 100,000 population). This is because they do not expect a significant change in use of the technology as a result of the amendments to the guidance.

Diagnostics Guidance (DGs)

None published this month.

NICE Quality Standards

Suicide prevention QS189

This quality standard covers ways to reduce suicide and help people bereaved or affected by suicide. It describes high-quality care in priority areas for improvement.

Multiple pregnancy: twin and triplet pregnancies QS46 (update)

This quality standard covers the additional antenatal care for women who are pregnant with twins or triplets that is offered alongside routine antenatal care. It describes high-quality care in priority areas for improvement.

In September 2019, the timeframes in quality statements 1, 2 and 8 were updated to reflect changes to the NICE guideline on twin and triplet pregnancy.

Lung cancer in adults QS17 (update)

This quality standard covers diagnosing and managing lung cancer in adults (aged 18 and over). It describes high-quality care in priority areas for improvement.

In September 2019, the statement on access to radiotherapy was amended to clarify the population covered by the statement.

Current NICE consultations

Title / link	End date of consultation
Violence and aggression: short-term management in mental health, health and community settings	02/10/2019
Faltering growth	02/10/2019
Community pharmacies: promoting health and wellbeing	02/10/2019
Fetal alcohol spectrum disorder	08/10/2019
Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management	16/10/2019
Neonatal parenteral nutrition	18/10/2019
Nintedanib for treating progressive fibrosing interstitial lung disease [ID1599]	21/10/2019
Fetoscopic prenatal repair for open neural tube defects in the foetus	24/10/2019
Open prenatal repair for open neural tube defects in the fetus	24/10/2019
Tinnitus: assessment and management	01/11/2019