NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: August 2021

Hyperlinks to the relevant NICE web page are included below.

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 existing NICE 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.

August 2021: NICE corrected an error in the practical info section of the recommendations on corticosteroids. The dose of prednisolone for children with a greater than 44-week corrected gestational age is 1 mg/kg.

Technology Appraisals (TAs)

Pemigatinib for treating relapsed or refractory advanced cholangiocarcinoma with FGFR2 fusion or rearrangement TA722

Recommendations

Pemigatinib is **recommended**, within its marketing authorisation, as an option for treating locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that has progressed after systemic therapy in adults. It is recommended only if the company provides pemigatinib according to the commercial arrangement.

The technology

Cholangiocarcinoma is cancer of the bile duct. It mainly affects people aged over 65. Most people already have advanced cholangiocarcinoma when they are diagnosed because early disease is often asymptomatic. When symptoms occur, they include jaundice, weight loss, pain, sickness and fever.

Cholangiocarcinoma can be classified into 3 subtypes, depending on which part of the bile duct the cancer starts in. Intrahepatic cholangiocarcinoma starts in the bile ducts inside the liver, peri-hilar cholangiocarcinoma starts just outside the liver and distal cholangiocarcinoma starts in the bile ducts near the bowel.

Surgery is currently the only curative treatment for cholangiocarcinoma. When surgery is not an option, people may receive chemotherapy or stent insertion. The most commonly used first chemotherapy regimen for cholangiocarcinoma is gemcitabine and cisplatin. Other chemotherapy treatments that may be used are capecitabine, fluorouracil and oxaliplatin.

Pemigatinib has a conditional marketing authorisation for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Financial factors

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources because the population size is small. It is estimated around 50 people per year in England are eligible for treatment with pemigatinib. Current treatment is active symptom control with or without chemotherapy. There may be additional costs incurred for FGFR2 testing which is not currently done for this population group.

Pemigatinib has a discount that is commercial in confidence.

Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome TA139 (update)

Recommendations

Continuous positive airway pressure (CPAP) is **recommended** as a treatment option for adults with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAHS).

August 2021: The recommendation on continuous positive airway pressure (CPAP) for mild obstructive sleep apnoea/hypopnoea syndrome (OSAHS) has been updated and replaced by recommendation 1.5.2 on CPAP for mild OSAHS in the NICE guideline on obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s.

The diagnosis and treatment of OSAHS, and the monitoring of the response, should be carried out by a specialist service with appropriately trained medical and support staff.

The technology

Obstructive sleep apnoea/hypopnoea syndrome (OSAHS) can be defined as the coexistence of excessive daytime sleepiness with irregular breathing at night. OSAHS occurs because the upper airway collapses intermittently.

When the person falls asleep the muscle-tone in the upper pharyngeal airway decreases leading to upper airway narrowing. This produces an increase in inspiratory effort in an attempt to overcome this airway narrowing, which then leads to a transient arousal from deep sleep to wakefulness or a lighter sleep which allows restoration of normal airway muscular tone and calibre. These upper airway collapses occur repeatedly throughout the night leading to fragmentation of normal sleep architecture

and a reduction in the quality of sleep with the generation of restless, disturbed and unsatisfying sleep.

A CPAP device consists of a unit that generates airflow, which is directed to the airway via a mask. Positive pressure is generated by the airflow, which prevents upper airway collapse. For CPAP treatment to be effective the person must always wear their device when they go to sleep.

There are two types of CPAP devices. Fixed CPAP devices deliver air at constant pressure throughout the night, and the person will continue to receive this pressure until a further titration study is performed to determine whether the set pressure is still appropriate. Auto-titrating CPAP devices continually adjust the pressure delivered throughout the night, with the aim of improving comfort and thus adherence.

Financial factors

The price of CPAP devices ranges from £250 to £550. Costs may vary in different settings because of negotiated procurement discounts.

The lifespan of a CPAP device has been reported to be approximately 7 years. The lifespan of a mask is 6 to 12 months.

Abiraterone for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer TA721

Recommendations

Abiraterone with prednisone or prednisolone plus androgen deprivation therapy (ADT) is **not recommended**, within its marketing authorisation, for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer in adults.

This recommendation is not intended to affect treatment with abiraterone with prednisone or prednisolone plus ADT 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

Prostate cancer is a disease in which tumours develop in the prostate, a gland in the male reproductive system. Its cause is thought to be multi-factorial, involving both environmental and genetic factors. Prostate cancer often leads to bone metastases, typically in the spine, pelvis and rib cage.

Hormone-naïve refers to people that are about to start (or who have started within the last 12 weeks) treatment with ADT for the treatment of metastatic prostate cancer.

For metastatic prostate cancer, NICE clinical guideline 175 recommends androgen deprivation therapy, specifically, bilateral orchidectomy (removal of the testicles) or continuous luteinising hormone-releasing hormone agonist therapy. For people who are willing to accept the adverse impact on overall survival and gynaecomastia (breast swelling) in the hope of retaining sexual function, the guideline recommends offering anti-androgen monotherapy with bicalutamide. NHS England commissions docetaxel chemotherapy for treating metastatic prostate cancer in people who are about to start, or who recently started, androgen deprivation therapy.

Abiraterone with prednisone or prednisolone has a UK marketing authorisation for treating newly diagnosed high-risk metastatic hormone-sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT). In LATITUDE, a key trial in this appraisal, high-risk prognosis was defined as having at least 2 of the following 3 risk factors: a Gleason score of 8 or more; 3 or more lesions on bone scan; and measurable visceral metastasis (excluding lymph node disease).

Financial factors

This technology is commissioned by NHS England.

Treatment for newly diagnosed high-risk hormone-sensitive metastatic prostate cancer in the NHS in England includes ADT alone, docetaxel plus ADT and, as of July 2021, enzalutamide plus ADT.

There is a proposed commercial arrangement that would make abiraterone available to the NHS at a discount. However even accounting for this, the cost-effectiveness estimates of either abiraterone in combination compared with ADT alone or with docetaxel plus ADT for the whole population are higher than what NICE considers cost effective. There are no appropriate cost-effectiveness estimates for when docetaxel cannot be used or is unsuitable. Therefore, abiraterone is not recommended for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer.

Chlormethine gel for treating mycosis fungoides-type cutaneous T-cell lymphoma TA720

Recommendations

Chlormethine gel is **recommended** as an option for treating early stage (stage 1A, 1B, and 2A) mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) in adults, only if the company provides chlormethine gel according to the commercial arrangement.

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

The technology

Lymphomas are cancers of the lymphatic system. They are broadly divided into Hodgkin's and non-Hodgkin's lymphomas. Cutaneous T-cell lymphoma is a rare type of non-Hodgkin's lymphoma that affects the skin. It is caused by the uncontrolled growth of T-lymphocytes within the skin. Many types of cutaneous T-cell lymphoma start as flat, scaly, oval patches or plaques on the skin, which progress to skin tumours, and are often itchy and sometimes painful.

Some people with cutaneous T-cell lymphoma experience swelling of the lymph nodes. Within the group of cutaneous T-cell lymphoma, there are distinct subtypes. Mycosis fungoides is the most common type of cutaneous T-cell lymphoma. It is usually a very slow-growing type of lymphoma that often only affects the skin and can stay under control for many years.

Current management of cutaneous T-cell lymphoma consists of skin directed therapies and systemic therapies. Skin directed therapies (SDT) are the main treatment for early-stage disease and include SDT photo therapy (such as psoralen and ultraviolet A treatment [PUVA] and narrow band ultraviolet B treatment [UVB]), total skin electron beam therapy, topical chemotherapy agents, and topical corticosteroids.

Chlormethine gel is indicated for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL) in adult patients.

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 similar. Chlormethine gel has a discount, the size of which is commercial in confidence.

Highly specialised technology guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Babies, children and young people's experience of healthcare NG204

This guideline describes good patient experience for babies, children and young people, and makes recommendations on how it can be delivered. It aims to make sure that all babies, children and young people using NHS services have the best possible experience of care. It is recognised that parents and carers play a key role, and where appropriate, we took their views into account when developing the recommendations.

The guideline includes recommendations on:

- overarching principles of care
- communication and information
- planning healthcare
- consent, privacy and confidentiality
- advocacy and support
- improving healthcare experience, including healthcare environments
- accessibility, continuity and coordination

Chronic kidney disease: assessment and management NG203

This guideline covers care and treatment for people with, or at risk of, chronic kidney disease (CKD). It aims to prevent or delay the progression, and reduce the risk of complications and cardiovascular disease. It also covers managing anaemia and hyperphosphataemia associated with chronic kidney disease.

There are new and updated recommendations on:

- investigations for CKD
- classification of CKD
- frequency of monitoring
- risk assessment, referral criteria and shared care
- blood pressure control
- medicines for CKD
- phosphate binders to manage mineral and bone disorders
- glomerular filtration rate for diagnosing anaemia associated with CKD
- intravenous iron for treating anaemia associated with CKD

These supplement the existing recommendations on:

- information and education for people with CKD
- diagnosing and assessing anaemia associated with CKD
- managing anaemia associated with CKD
- assessing and optimising erythropoiesis in people with anaemia
- monitoring anaemia treatment

Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s NG202

This guideline covers the diagnosis and management of obstructive sleep apnoea/hypopnoea syndrome (OSAHS), obesity hypoventilation syndrome (OHS) and chronic obstructive pulmonary disease with OSAHS (COPD–OSAHS overlap syndrome) in people over 16. It aims to improve recognition, investigation and treatment of these related conditions.

The guideline contains recommendations on:

- OSAHS initial assessment, diagnosis and management
- OHS initial assessment, diagnosis and management
- COPD–OSAHS overlap syndrome initial assessment, diagnosis and management
- Providing information for people with OSAHS, OHS or COPD–OSAHS overlap syndrome

Antenatal care NG201

This guideline covers the routine antenatal care that women and their babies should receive. It aims to ensure that pregnant women are offered regular check-ups, information and support. NICE has also published a guideline on postnatal care, which covers the topics of emotional attachment and baby feeding.

The guideline contains recommendations on:

- Organisation and delivery of antenatal care

- Routine antenatal clinical care
- Information and support for pregnant women and their partners
- Interventions for common problems during pregnancy

Bronchiolitis in children: diagnosis and management NG9 (update)

This guideline covers diagnosing and managing bronchiolitis in babies and children. It aims to help healthcare professionals diagnose bronchiolitis and identify if babies and children should be cared for at home or in hospital. It describes treatments and interventions that can be used to help with the symptoms of bronchiolitis.

August 2021: NICE reviewed the evidence and updated the recommendations on oxygen saturation thresholds for referral to hospital, admission, management and timing of discharge.

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)

Hysteroscopic mechanical tissue removal (hysteroscopic morcellation) for uterine fibroids IPG704

This guidance replaces NICE IPG522 on hysteroscopic morcellation of uterine leiomyomas (fibroids).

Recommendations

Evidence on the safety of hysteroscopic mechanical tissue removal (hysteroscopic morcellation) for uterine fibroids shows there are well recognised, infrequent but potentially serious side-effects. Evidence on its efficacy 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 hysteroscopic mechanical tissue removal (hysteroscopic morcellation) for uterine fibroids 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.

The procedure should only be done by clinicians with specific training in this technique, including fluid management.

Further research should report details of patient selection and patient reported outcomes, particularly symptom relief.

The condition

Uterine fibroids (also known as uterine leiomyomas or myomas) are benign tumours of the uterus. They can be asymptomatic or cause symptoms including heavy periods or bleeding between periods. They can be associated with fertility problems and miscarriage.

Treatment depends on whether the fibroids cause symptoms, and if the person would like to become pregnant in the future. For symptomatic fibroids, treatment options include medication, interventional radiology and surgery. Interventional radiology treatments include uterine artery embolisation and MRI-guided focused ultrasound. Surgery includes hysterectomy, myomectomy, endometrial ablation techniques and myolysis.

This procedure is used for submucosal fibroids, which develop in the muscle layer beneath the inner lining of the uterus and grow into the uterine cavity. This includes pedunculated fibroids, which are attached to the uterus with a narrow stalk of tissue.

The procedure

Hysteroscopic mechanical tissue removal (hysteroscopic morcellation) aims to remove submucosal uterine fibroids under visual guidance using a hysteroscope inserted into the uterus through the cervix. It is intended to reduce the risk of traumatic injury to the uterus associated with traditional procedures. An intended advantage of the procedure over thermal ablation techniques is avoiding the risk of thermal injury.

The procedure may be done under local, regional, or general anaesthesia, typically as a day-case procedure. A hysteroscope is inserted into the uterus through the cervix and saline is pumped thorough a small channel in the hysteroscope to distend the uterus.

A morcellator is passed through the hysteroscope and used to cut and simultaneously aspirate the morcellated fibroid tissue. The aspirated tissue can be collected for histological analysis.

Laparoscopic removal of uterine fibroids with power morcellation IPG703

Recommendations

Evidence on the safety of laparoscopic removal of uterine fibroids with power morcellation shows potentially serious complications. In particular there is a risk of spreading undiagnosed malignant tissue, which has higher prevalence in people who are postmenopausal or over 50. Evidence on the procedure's efficacy is limited in quantity. Therefore:

- For people who are postmenopausal or over 50, this procedure **should not be used**.
- For people who are premenopausal or 50 or under, this procedure should only be used with **special arrangements** for clinical governance, consent and audit or research.

Further research should report details of patient selection, surgical technique (including any containment system used) and long-term outcomes.

Clinicians wishing to do laparoscopic removal of uterine fibroids with power morcellation in people who are premenopausal or 50 or under 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. Also see the Royal College of Obstetricians and Gynaecologists' advice on obtaining consent from women having this procedure.
- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these. Also see the Royal College of Obstetricians and Gynaecologists' information for patients who may be considering this procedure.
- 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 procedures 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 by a surgeon with specific training in laparoscopic surgery. When an in-bag technique is needed, the surgeon should also have specific training in using containment systems.

The condition

Uterine fibroids (also known as uterine leiomyomas or myomas) are benign tumours of the uterus. They can be asymptomatic or can cause symptoms including heavy periods or intermenstrual bleeding. They can be associated with fertility problems and miscarriage.

Treatment depends on whether the fibroids cause symptoms, and if the person would like to become pregnant in the future. For symptomatic fibroids, treatment options include medication, interventional radiology and surgery. Interventional radiology treatments include uterine artery embolisation and MRI-guided focused ultrasound. Surgery includes hysterectomy, myomectomy, endometrial ablation techniques and myolysis.

The procedure

Laparoscopic surgery with power morcellation allows uterine fibroids to be cut into smaller pieces so they can be removed laparoscopically and without the need for a laparotomy. The procedure aims to reduce symptoms caused by fibroids.

Laparoscopic removal of uterine fibroids with power morcellation is done with the patient under general anaesthesia. During laparoscopic surgery and under direct visualisation an electrosurgical morcellator is introduced through a small incision into the abdomen and used to cut the uterine fibroid into smaller pieces. If a hysterectomy is planned, morcellation can be used to also remove part or all of the uterus. The fragments are removed through the morcellation cannula. The removed tissue should be sent for histological analysis. To reduce the risk of disseminating benign and malignant uterine tissue, the tissue can be contained in an insufflated sterile bag while being morcellated within the abdomen.

Magnetic resonance therapy for knee osteoarthritis IPG702

Recommendations

Evidence on the safety of magnetic resonance therapy for knee osteoarthritis shows no major safety concerns. Evidence on efficacy is inadequate in quality and quantity and shows no benefit over placebo. Therefore, this procedure should not be used unless it is part of a **research study**.

Further research should be in the form of appropriately powered randomised controlled trials comparing the procedure with placebo. It should report patient selection and treatment protocols, including the number of sessions and magnetic field strength.

The condition

Osteoarthritis of the knee is the result of progressive deterioration of the articular cartilage and menisci of the joint, usually because of trauma and wear and tear. This leads to exposure of the bone surface. Symptoms include pain, stiffness, swelling and difficulty walking. Acute exacerbations of pain are common and usually self-limiting after 14 days. Only a small number of patients develop progressive symptoms needing treatment.

Treatment depends on the severity of the symptoms. Conservative treatments include analgesics and corticosteroid injections to relieve pain and inflammation, and

physiotherapy and prescribed exercise to improve function and mobility. When symptoms are severe, surgery may be indicated: options include upper tibial osteotomy and unicompartmental or total knee replacement.

The procedure

Magnetic resonance therapy (MRT) for osteoarthritis is a non-invasive procedure that uses a special device to administer electromagnetic energy to an osteoarthritic joint. A range of devices with different physical designs are available. The aim is to relieve the symptoms and to improve the osteoarthritis by stimulating the cartilage cells.

MRT is done in an outpatient setting. During the procedure, the patient lies on the couch and a section of the MRT device slides over the knee. The device generates electromagnetic fields which are targeted to the cartilaginous tissue in the affected joint. The aim is to promote joint repair and relieve the symptoms of osteoarthritis. Each treatment lasts 60 minutes. Depending on the severity of the disease and MRT therapy device, a course of treatment typically consists of 5 to 10 treatment sessions on consecutive days.

Medical Technologies Guidance (MTGs)

None published this month.

Diagnostics Guidance (DGs)

None published this month.

NICE Quality Standards

Venous thromboembolism in adults QS201

This quality standard covers reducing the risk of venous thromboembolism (VTE) in people aged 16 and over who are in hospital. It also covers diagnosing and treating VTE in all people aged 18 and over. It describes high-quality care in priority areas for improvement.

It updates and replaces the quality standards on venous thromboembolism in adults: reducing the risk in hospital (June 2010), and venous thromboembolism in adults: diagnosis and management (March 2013). The topic was identified for update following the annual review of quality standards. The review identified:

- changes in the priority areas for improvement
- new guidance on venous thromboembolic diseases: diagnosis, management and thrombophilia testing (NG158)
- that the quality standards on venous thromboembolism in adults: reducing the risk in hospital (QS3) and venous thromboembolism in adults: diagnosis and management (QS29) should be combined.

Antenatal care QS22 (update)

This quality standard covers care for healthy women and their babies during pregnancy (up to 42 weeks). It covers routine antenatal care in primary, community and hospital settings. It describes high-quality care in priority areas for improvement.

August 2021: NICE made changes to align this quality standard with the updated NICE guideline on antenatal care.

Inducing labour QS60 (update)

This quality standard covers the induction of labour in hospital outpatient or inpatient settings. It includes advice and care for pregnant women who are considering or having induction of labour. It describes high-quality care in priority areas for improvement.

August 2021: NICE made changes to align this quality standard with the updated NICE guideline on antenatal care.

Current NICE consultations

Title / link	End date of consultation
Brain tumours (primary) and brain metastases in adults	06/09/2021
Rehabilitation after traumatic injury	08/09/2021
Headaches	09/09/2021
MT582 AnaConDa-S for sedation with volatile anaesthetics in intensive care	13/09/2021
Disabled children and young people up to 25 with severe complex needs: integrated service delivery and organisation across health, social care and education	14/09/2021
Daratumumab in combination for untreated multiple myeloma when stem cell transplant is suitable [ID1510]	17/09/2021
Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer (CDF review TA528) [ID1644]	17/09/2021
Nivolumab with ipilimumab for untreated unresectable malignant pleural mesothelioma [ID1609]	20/09/2021
Cenobamate for focal onset seizures in epilepsy [ID1553]	21/09/2021