NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: August 2020

Hyperlinks to the relevant NICE web page are included below.

NICE rapid COVID-19 guidelines

COVID-19 rapid guideline: gastrointestinal and liver conditions treated with drugs affecting the immune response NG172 (update)

The purpose of this guideline is to maximise the safety of children and adults who have gastrointestinal or liver conditions treated with drugs affecting the immune response during the COVID 19 pandemic. It also aims to protect staff from infection and enable services to make the best use of NHS resources.

August 2020: NICE updated recommendations on modifications to care in line with their COVID-19 rapid guideline on arranging planned care in hospitals and diagnostic services.

COVID 19 rapid guideline: renal transplantation NG178 (update)

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.

August 2020: NICE added recommendations for regional networks on responding to changes in local prevalence of COVID-19. NICE aligned recommendations for donors and recipients with their COVID-19 guideline on arranging planned care in hospitals and diagnostic services.

COVID-19 rapid guideline: children and young people who are immuno-compromised NG174 (update)

The purpose of this guideline is to maximise the safety of children and young people who are immunocompromised during the COVID-19 pandemic. It also aims to protect staff from infection and enable services to make the best use of NHS resources.

August 2020: NICE updated the recommendation on safeguarding to remove a link to government guidance that has been withdrawn.

COVID-19 rapid guideline: dialysis service delivery NG160 (update)

The purpose of this guideline is to maximise the safety of patients on dialysis, while protecting staff from infection. It will also enable dialysis services to make the best use of NHS resources and match the capacity of dialysis services to patient needs if these become limited because of the COVID-19 pandemic.

August 2020: NICE changed the recommendation on how long people need to stay in the cohort of patients known to have COVID-19.

Technology Appraisals (TAs)

Entrectinib for treating NTRK fusion-positive solid tumours TA644

Recommendations

Entrectinib is **recommended for use within the Cancer Drugs Fund** as an option for treating neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumours in adults and children 12 years and older if:

- the disease is locally advanced or metastatic or surgery could cause severe health problems and
- they have not had an NTRK inhibitor before and
- they have no satisfactory treatment options.

  It is recommended only if the conditions in the managed access agreement for entrectinib are followed.

This recommendation is not intended to affect treatment with entrectinib that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop. For children and young people, this decision should be made jointly by the clinician and the child or young person or their parents or carers.

The technology

There is no standard treatment for NTRK fusion-positive solid tumours, so current treatment is based on where in the body the cancer starts. Entrectinib is a histology-independent treatment. This means that it targets a genetic alteration, NTRK gene fusion, that is found in many different tumour types irrespective of where the cancer starts.

Entrectinib is indicated as monotherapy for the treatment of adult and paediatric patients 12 years of age and older, with solid tumours expressing a NTRK gene fusion who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity and who have not received a prior NTRK inhibitor who have no satisfactory treatment options.

Financial factors

This technology is commissioned by NHS England.

NICE estimates that 80 to 190 people per year in England with NTRK fusion-positive solid tumours, and who have had all other licensed treatments, would be eligible for treatment with entrectinib.

Entrectinib will be available to the NHS in line with the managed access agreement with NHS England. As part of this, NHS England and Roche have a commercial arrangement (simple discount patient access scheme and a managed access agreement including a commercial access agreement). This makes entrectinib available to the NHS with a discount, the size of which is commercial in confidence.

The resource impact of entrectinib will be covered by the Cancer Drugs Fund budget. The cost of genetic testing is met from genomics funding that is held separately within the Cancer Drugs Fund. 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.

Entrectinib for treating ROS1-positive advanced non-small-cell lung cancer TA643

Recommendations

Entrectinib is **recommended**, within its marketing authorisation, as an option for treating ROS1-positive advanced non-small-cell lung cancer (NSCLC) in adults who have not had ROS1 inhibitors. It is recommended only if the company provides entrectinib according to the commercial arrangement.

The technology

Entrectinib is an oral selective inhibitor of the TRK family of proteins (TRKA, TRKB and TRKC), proto-oncogene tyrosineprotein kinase (ROS1) and anaplastic lymphoma kinase (ALK). Entrectinib turns off the signalling pathway that allows TRK, ROS1 and ALK fusionpositive cancers to grow.

Entrectinib is indicated as monotherapy for the treatment of adult patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC) not previously treated with ROS1 inhibitors.

Financial factors

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources because the ROS1 gene fusion is rare, with around 40 people per year in England currently accessing an alternative treatment. Entrectinib is a further treatment option with no anticipated increase in the eligible population.

Entrectinib has a commercial arrangement which makes it available to the NHS with a discount. The size of the discount is commercial in confidence.

Gilteritinib for treating relapsed or refractory acute myeloid leukaemia TA642

Recommendations

Gilteritinib monotherapy is **recommended** as an option for treating relapsed or refractory FLT3-mutation-positive acute myeloid leukaemia (AML) in adults only if the company provides gilteritinib according to the commercial arrangement.

Gilteritinib should not be given as maintenance therapy after a haematopoietic stem cell transplant.

These recommendations are not intended to affect treatment with gilteritinib 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

Relapsed or refractory FLT3-mutation-positive AML is usually treated with salvage chemotherapy (a type of chemotherapy offered when a first course of chemotherapy has not worked, or the disease has come back after treatment).

Gilteritinib is an alternative treatment taken as an oral tablet at home. Gilteritinib is indicated as monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia (AML) with a FLT3 mutation.

Financial factors

This technology is commissioned by NHS England.

NICE estimates that 440 people in England with relapsed or refractory FLT3 mutation-positive AML are eligible for treatment with gilteritinib, and 340 people will receive gilteritinib from year 2021/22 onwards once uptake has reached 77%. This equates to 10 people in Devon, with 8 people receiving gilteritinib from year 2021/22 onwards.

Brentuximab vedotin in combination for untreated systemic anaplastic large cell lymphoma TA641

Recommendations

Brentuximab vedotin with cyclophosphamide, doxorubicin and prednisone (CHP) is **recommended**, within its marketing authorisation, as an option for untreated systemic anaplastic large cell lymphoma in adults. It is only recommended if the company provides brentuximab vedotin according to the commercial arrangement.

The technology

Brentuximab vedotin is an antibody-drug conjugate that selectively targets tumour cells expressing the CD30 protein.

Brentuximab vedotin with cyclophosphamide, doxorubicin and prednisone (CHP) is indicated for adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL).

Financial factors

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources because the eligible population is expected to be around 100 people per year in England.

Brentuximab vedotin has a discount that is commercial in confidence.

Treosulfan with fludarabine for malignant disease before allogeneic stem cell transplant TA640

Recommendations

Treosulfan with fludarabine is **recommended** as an option for conditioning treatment before allogeneic haematopoietic stem cell transplant (allo-HSCT) for people with malignant diseases for whom a reduced intensity regimen, such as low-dose busulfan with fludarabine, would be suitable.

The technology

People with malignant diseases having an allo-HSCT need to have conditioning treatment first to prepare their bone marrow. If they cannot tolerate high-intensity myeloablative conditioning, they can have reduced-intensity conditioning such as low-dose busulfan with fludarabine.

Treosulfan in combination with fludarabine is indicated as part of conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (alloHSCT) in adult patients with malignant and non-malignant diseases, and in paediatric patients older than 1 month with malignant diseases.

Financial factors

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources because the overall incremental cost of treatment is low and the population size is small.

Highly specialised technology guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

The recommendations in these guidelines were developed before the coronavirus pandemic.

Rehabilitation for adults with complex psychosis NG181

This guideline covers mental health rehabilitation for adults with complex psychosis. It aims to ensure people can have rehabilitation when they need it and promotes a positive approach to long-term recovery. It includes recommendations on organising rehabilitation services, assessment and care planning, delivering programmes and interventions, and meeting people's physical healthcare needs.

This guideline includes recommendations on:

- who should be offered rehabilitation
- principles of rehabilitation
- organising the rehabilitation pathway, improving access and delivering services

- a recovery-orientated approach
- assessment, care planning and review
- programmes and interventions
- adjustments to mental health treatments in rehabilitation
- physical healthcare

Perioperative care in adults NG180

This guideline covers care for adults (aged 18 and over) having elective or emergency surgery, including dental surgery. It covers all phases of perioperative care, from the time people are booked for surgery until they are discharged afterward. The guideline includes recommendations on preparing for surgery, keeping people safe during surgery and pain relief during recovery.

This guideline includes recommendations on:

- information and support for people having surgery
- enhanced recovery programmes
- preoperative care
- intraoperative care
- postoperative care
- managing pain

Surgical site infections: prevention and treatment NG125 (update)

This guideline covers preventing and treating surgical site infections in adults, young people and children who are having a surgical procedure involving a cut through the skin. It focuses on methods used before, during and after surgery to minimise the risk of infection.

August 2020: NICE added links to the NICE guideline on perioperative care in adults for additional recommendations on intravenous fluids, cardiac monitoring and blood glucose control in adults.

Anaphylaxis: assessment and referral after emergency treatment CG134 (update)

This guideline covers assessment and referral for anaphylaxis. It aims to improve the quality of care for people with suspected anaphylaxis by detailing the assessments that are needed and recommending referral to specialist allergy services.

August 2020: NICE added advice on prescribing adrenaline injectors before discharge after emergency treatment.

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)

Implanted vagus nerve stimulation for treatment-resistant depression IPG679

This guidance replaces NICE interventional procedures guidance on vagus nerve stimulation for treatment-resistant depression (IPG330).

Recommendations

Evidence on the safety of implanted vagus nerve stimulation for treatment-resistant depression raises no major safety concerns, but there are frequent, well-recognised side effects. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE website.

Clinicians wishing to do implanted vagus nerve stimulation for treatment-resistant depression should:

- Inform the clinical governance leads in their NHS trusts.
- Give patients clear written 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.
- Audit and review clinical outcomes of all patients having the procedure. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion).

NICE encourages further research into implanted vagus nerve stimulation for treatment-resistant depression, in the form of randomised controlled trials with a placebo or sham stimulation arm. Studies should report details of patient selection. Outcomes should include validated depression rating scales, patient-reported quality of life, time to onset of effect and duration of effect, and any changes in concurrent treatments.

The condition

Depression is characterised by low mood, loss of interest and enjoyment in life, and a range of associated emotional, cognitive, physical and behavioural symptoms. Depression is treatment-resistant when symptoms have not improved after at least 2 standard treatments.

The diagnosis and management of depression is described in the NICE guideline for depression in adults and the NICE guideline for depression in children and young people. Standard treatment for depression includes antidepressants or psychological therapies (including cognitive behavioural therapies) or a combination of both. In severe depression when multiple treatments have failed, electroconvulsive therapy or other forms of neurostimulation are sometimes used.

The procedure

The aim of implanted vagus nerve stimulation for treatment-resistant depression is to reduce symptoms and improve mood by periodic stimulation of the vagus nerve.

The procedure is done using general or local anaesthesia. An incision is made on the left side of the neck and the left vagus nerve is identified. A stimulator electrode is put around the nerve and the leads of the electrode are guided under the skin to the left chest wall. They are attached to a pulse generator unit, which is implanted into a subcutaneous pocket. The stimulator settings can be adjusted or turned off using an external (wireless) programming device.

Deep brain stimulation for refractory epilepsy in adults IPG678

This guidance replaces NICE interventional procedures guidance on deep brain stimulation for refractory epilepsy (IPG416).

Recommendations

Evidence on the safety and efficacy of deep brain stimulation for refractory epilepsy in adults differs according to the site of stimulation:

- For anterior thalamic targets the evidence is limited in quantity and quality, therefore this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE website.
- For targets other than the anterior thalamus the evidence is inadequate in quantity and quality, therefore this procedure should only be used in the **context of research**. Find out what only in research means on the NICE website.

Clinicians wishing to do deep brain stimulation of anterior thalamic targets for refractory epilepsy in adults should:

- Inform the clinical governance leads in their NHS trusts.
- Give patients clear written 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.
- Audit and review clinical outcomes of all patients having the procedure. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

Patient selection should be done by a multidisciplinary team experienced in managing epilepsy including a neurologist, neurophysiologist and neurosurgeon.

The procedure should only be done in neurosurgery centres that specialise in managing epilepsy.

Further research should describe patient selection and clearly define the target area of the brain. Outcomes should include reduction in seizure frequency and improvement in the epilepsy seizure outcome scale, quality of life, reduction in concomitant medication and hospital admissions.

The condition

Epilepsy is a neurological condition characterised by episodes of abnormal electrical activity in the brain which cause recurrent seizures. The seizures can be focal or generalised.

The main treatment for epilepsy is anti-epileptic drugs taken to prevent or reduce the occurrence of seizures. However, many people have drug-resistant (refractory) epilepsy. They experience frequent seizures and are at risk of status epilepticus and sudden unexpected death in epilepsy.

Surgery may be considered for refractory epilepsy. Surgical options include open surgical resection or disconnection, neuroablation or neuromodulation.

The procedure

Deep brain stimulation involves implanting electrodes into specific target areas of the brain. Although the mechanisms of action are not fully understood, the aim of the procedure is to reduce or suppress seizure frequency. A potential advantage of the procedure is its reversibility. It is an option for some patients with medically refractory epilepsy when resective surgery is not indicated.

The procedure is done using general or local anaesthesia. A stereotactic frame may be used. Imaging (MRI or CT) is used to identify the target area of the brain. One or more small holes are drilled in the skull and electrodes are implanted into the target area.

A neurostimulator is surgically placed into a subcutaneous pocket below the clavicle. The electrodes are connected to the neurostimulator by leads that are tunnelled under the skin of the neck and scalp. Postoperative imaging is usually used to confirm the location of the electrodes. A handheld remote-control programming unit is used to turn the neurostimulator on or off, adjust stimulation parameters, and monitor activity.

Electrical stimulation to improve muscle strength in chronic respiratory conditions, chronic heart failure and chronic kidney disease IPG677

Recommendations

Evidence on the safety of electrical stimulation to improve muscle strength in chronic respiratory conditions, chronic heart failure and chronic kidney disease shows no major safety concerns.

- For people who are having an acute exacerbation of their chronic condition and are unable to exercise, evidence of efficacy is adequate to support the use of this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE website.
- For people who are able to exercise, evidence on efficacy is inadequate in quality. Therefore, this procedure should only be used in the **context of research**. Find out what only in research means on the NICE website.

Further research should include long term, suitably powered and appropriately controlled randomised trials. These should report details of patient selection, and type and duration of treatment. Outcomes should include quality of life, social functioning and physiological measures.

The condition

Chronic respiratory conditions, chronic heart failure and chronic kidney disease can cause impaired muscle function and weakness.

Rehabilitation is described in NICE's guidelines on rehabilitation after critical illness, chronic obstructive pulmonary disease and chronic heart failure. Management for muscle weakness or dysfunction caused by chronic respiratory conditions, chronic heart failure or chronic kidney disease includes lifestyle change, medication (including oxygen therapy), rehabilitation (such as pulmonary rehabilitation or cardiac rehabilitation) and treating the underlying conditions.

The procedure

Electrical stimulation produces muscle contractions that aim to mimic exercise training. Small electrical impulses are applied to nerves supplying groups of muscles typically in either the arms or legs, using self-adhesive electrodes applied to the skin and connected to an electrical stimulator. This causes the muscles supplied by the nerve to contract and relax. A typical programme consists of 30 to 60 minutes of stimulation.

Transcranial magnetic stimulation for obsessive-compulsive disorder IPG676

Recommendations

Evidence on the safety of transcranial magnetic stimulation for obsessive-compulsive disorder raises no major safety concerns. However, evidence on its efficacy is inadequate in quantity and quality. Therefore, this procedure should only be used in the **context of research**.

Research should ideally be in the form of pre-registered, adequately powered, randomised controlled trials. It should report details of patient selection, including the use of concurrent therapies, type, duration and frequency of stimulation, and the intended target in the brain. Outcomes should include improvement in symptoms, quality of life and duration of effect.

The condition

Obsessive-compulsive disorder is a mental health condition in which a person has obsessive thoughts (repeated, unwanted and unpleasant thoughts, images or urges). The person feels compelled to carry out compulsive (repetitive) behaviours to try to relieve the unpleasant feelings brought on by the obsessive thoughts.

NICE's clinical guideline on obsessive-compulsive disorder and body dysmorphic disorder describes the treatment of the disorder. Treatment options include psychological interventions and drug treatment (typically, selective serotonin reuptake inhibitors).

The procedure

Transcranial magnetic stimulation (TMS) is done with the patient awake and sitting in a comfortable chair. The operator places an electromagnetic coil over a specific region

of the head. The coil delivers electromagnetic pulses through the skull that stimulate neurons (brain cells) by inducing small electrical currents within the brain. Different areas of the brain may be targeted, and a variety of stimulation protocols may be used. Treatment with TMS usually comprises daily sessions lasting about 30 minutes, for a few weeks. The aim is to reduce the symptoms of obsessive-compulsive disorder.

In repetitive TMS (rTMS), repetitive pulses of electromagnetic energy are delivered at various frequencies (low or high) or stimulus intensities. The intensity of stimulation is usually titrated against the minimum intensity needed to elicit a motor response when stimulating the motor cortex, known as the motor threshold. Determining the motor threshold for rTMS can be done visually or by using electromyography.

Conventional rTMS is repeated individual pulses at a pre-set interval (train of pulses), and theta-burst rTMS is repeated short bursts of pulses at a pre-set interval (train of bursts). Deep TMS stimulates deeper and broader brain regions compared with conventional rTMS.

Medical Technologies Guidance (MTGs)

None published this month.

Diagnostics Guidance (DGs)

High-sensitivity troponin tests for the early rule out of NSTEMI DG40

This guidance replaces the NICE diagnostics guidance on myocardial infarction (acute): early rule out using high-sensitivity troponin tests (DG15).

Recommendations

The following high-sensitivity troponin tests are **recommended** as options for the early rule out of non-ST-segment elevation myocardial infarction (NSTEMI) in people presenting to an emergency department with chest pain and suspected acute coronary syndrome:

- Access High-Sensitivity Troponin I Assay
- ADVIA Centaur High-Sensitivity Cardiac Troponin-I Assay
- Alinity High Sensitive Troponin-I assay
- ARCHITECT STAT High Sensitive Troponin-I assay
- Atellica IM High-Sensitivity Cardiac Troponin I Assay
- Dimension Vista High-Sensitivity Cardiac Troponin I Assay
- Dimension EXL High-Sensitivity Cardiac Troponin I Assay
- Elecsys Troponin T-high sensitive assay
- Elecsys Troponin T-high sensitive STAT assay
- VIDAS High sensitive Troponin I assay
- VITROS High Sensitivity Troponin I Assay.

The tests are recommended for use with different early rule-out test strategies alongside clinical judgement, including:

- A single sample on presentation using a threshold at or near the limit of detection, which will vary depending on the assay being used. If this sample is positive it should not be used to rule in NSTEMI.
- Multiple sample strategies, which typically include a sample at initial assessment followed by a second sample taken at 30 minutes to 3 hours (if clinically appropriate) and use of 99th percentile thresholds or thresholds at or near the limit of detection of the assay.

  Healthcare professionals should consider the likely time since the onset of symptoms when interpreting test results.

When NSTEMI is not ruled out using early rule-out test strategies, use NICE's guideline on recent-onset chest pain of suspected cardiac origin to help diagnose myocardial infarction, and consider using sex-specific thresholds at the 99th percentile.

Further research is recommended on the diagnostic performance of the TriageTrue High Sensitivity Troponin I test when using samples at point of care.

The tests

Cardiac troponin I and cardiac troponin T are biological markers of cardiac muscle death (cardiomyocyte necrosis). They are released into the circulation when damage to cardiac muscle has occurred. The optimum sensitivity of older (non-high-sensitivity) troponin assays for acute myocardial infarction occurs 10–12 hours after the onset of symptoms.

For many people, this results in the need for hospital admission and observation while serial troponin testing is carried out. To overcome this, high-sensitivity troponin assays have been developed. These can detect lower levels of troponin in the blood earlier than older standard assays, leading to improved early detection of acute myocardial infarction.

Using these high-sensitivity assays enables earlier detection of changes in troponin levels. This allows NSTEMI to be ruled out within 4 hours without the need for a hospital admission if test results are available within 3 hours of presentation to the emergency department or chest pain units. High-sensitivity assays are currently used in most hospitals.

Financial factors

Cardiological services for patients with NSTEMI are commissioned by CCGs.

NICE states that increased use of highly sensitive testing should reduce the number of people admitted to hospital with suspected NSTEMI. This will be a cash saving to commissioners and will give capacity benefits to providers. However, if any capacity released because of reduced admissions is immediately filled, these cash benefits will not be realised by commissioners.

Although the overall volume of tests is not expected to increase, there may be an increased pressure on labs to turn around the tests quickly.

NICE Quality Standards

These quality standards were developed before the coronavirus pandemic and are intended to support quality improvement as services return to normal.

Faltering growth QS197

This quality standard covers recognising and managing faltering growth in babies (aged up to 1 year) and preschool children (aged over 1 year). It describes high-quality care in priority areas for improvement.

Community pharmacies: promoting health and wellbeing QS196

This quality standard covers how community pharmacies can support the health and wellbeing of the local population. It describes high-quality care in priority areas for improvement.

Decision making and mental capacity QS194

This quality standard covers decision making in people aged 16 and over, using health and social care services who may lack capacity to make their own decisions (now or in the future). It aims to support implementation of the aims and principles of the Mental Capacity Act 2005 and relevant Codes of Practice. It is not a substitute for these.

Current NICE consultations

Title / link	End date of consultation
Secondary infection of common skin conditions including eczema: antimicrobial prescribing	04/09/2020
Chronic pain: assessment and management	14/09/2020
Fetal alcohol spectrum disorder	18/09/2020
The PLASMA system for transurethral resection of the prostate	21/09/2020
Abortion care	21/09/2020
Free-functioning gracilis transfer to restore upper limb function in brachial plexus injury	25/09/2020
Repetitive short pulse transscleral cyclophotocoagulation for glaucoma	25/09/2020
Cytoreduction surgery followed by hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis	25/09/2020