NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: December 2019

Hyperlinks to the relevant NICE web page are included below.

Technology Appraisals (TAs)

Cladribine for treating relapsing–remitting multiple sclerosis TA616

This guidance replaces NICE technology appraisal guidance 493 on cladribine tablets for treating relapsing–remitting multiple sclerosis.

Recommendations

Cladribine is **recommended** as an option for treating highly active multiple sclerosis in adults, only if the person has:

- rapidly evolving severe relapsing–remitting multiple sclerosis, that is with at least:
  - 2 relapses in the previous year and
  - 1 T1 gadolinium-enhancing lesion at baseline MRI or a significant increase in T2-lesion load compared with a previous MRI, or
- relapsing–remitting multiple sclerosis that has responded inadequately to treatment with disease-modifying therapy, defined as 1 relapse in the previous year and MRI evidence of disease activity.

This recommendation is not intended to affect treatment with cladribine 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

Cladribine tablets are indicated for the treatment of adult patients with highly active relapsing multiple sclerosis as defined by clinical or imaging features.

In the summary of product characteristics, the recommended cumulative dose is 3.5 mg/kg body weight over 2 years, taken as 1 treatment course of 1.75 mg/kg per year. Each treatment course consists of 2 treatment weeks, 1 at the beginning of the first month and 1 at the beginning of the second month of the respective treatment year. Each treatment week consists of 4 or 5 days on which a patient takes 10 mg or 20 mg (1 or 2 tablets) as a single daily dose, depending on body weight.

After completing the 2 treatment courses, no further cladribine treatment is needed in years 3 and 4.

Financial factors

This technology is commissioned by NHS England.

The Accelerated Access Collaborative (AAC) is supporting the rapid uptake of 7 high-potential technologies with full evidence bases that are already in the system. These products will enable patients to access new treatments faster and improve patients' lives but are not currently available to everyone who could benefit. Cladribine tablets are one of these products.

The AAC raised concerns that the requirement for gadolinium-enhancing MRI before treatment is a barrier to accessing cladribine tablets and uptake has been slow. Historically, safety concerns with gadolinium have been raised and although the specific agents of concern have been withdrawn from the market, there is still a perception that gadolinium is unsafe. Because of this, a review of TA493 has been done earlier than the scheduled review date.

Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome TA615

Recommendations

Cannabidiol with clobazam is **recommended** as an option for treating seizures associated with Lennox–Gastaut syndrome in people aged 2 years and older, only if:

- the frequency of drop seizures is checked every 6 months, and cannabidiol is stopped if the frequency has not fallen by at least 30% compared with the 6 months before starting treatment
- the company provides cannabidiol according to the commercial arrangement.

This recommendation is not intended to affect treatment with cannabidiol, with clobazam, 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 before this guidance was published, until they and their NHS clinicians 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 the child or young person's parents or carers.

The technology

Cannabidiol is licensed as adjunctive therapy for seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in conjunction with clobazam, for patients 2 years of age or older.

It is administered orally as 100 mg/ml cannabidiol solution. The recommended starting dosage is 2.5 mg/kg taken twice daily for 1 week. After 1 week, the dosage should be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day). Based on individual clinical response and tolerability, each dosage can be further increased in weekly increments of 2.5 mg/kg taken twice daily up to a maximum recommended dosage of 10 mg/kg twice daily (20 mg/kg/day). Any dosage increases above 10 mg/kg/day should take into account individual benefit and risk.

Financial factors

This technology is commissioned by NHS England.

NICE estimate that 4,100 people in England with seizures associated with Lennox–Gastaut syndrome are eligible for treatment with cannabidiol. The maximum uptake is estimated at 80% of the eligible population. 1,810 people will have cannabidiol in year 2024/25.

Cannabidiol has a discount to the list price that is commercial in confidence. The list price of cannabidiol has been agreed with the Department of Health and Social Care but is considered confidential by the company until January 2020.

Cannabidiol with clobazam for treating seizures associated with Dravet syndrome TA614

Recommendations

Cannabidiol with clobazam is **recommended** as an option for treating seizures associated with Dravet syndrome in people aged 2 years and older, only if:

- the frequency of convulsive seizures is checked every 6 months, and cannabidiol is stopped if the frequency has not fallen by at least 30% compared with the 6 months before starting treatment
- the company provides cannabidiol according to the commercial arrangement.

This recommendation is not intended to affect treatment with cannabidiol, with clobazam, 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 before this guidance was published, until they and their NHS clinicians 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 the child or young person's parents or carers.

The technology

Cannabidiol is licensed as adjunctive therapy for seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in conjunction with clobazam, for patients 2 years of age or older.

It is administered orally as 100 mg/ml cannabidiol solution. The recommended starting dosage is 2.5 mg/kg taken twice daily for 1 week. After 1 week, the dosage should be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day). Based on individual clinical response and tolerability, each dosage can be further increased in weekly increments of 2.5 mg/kg taken twice daily up to a maximum recommended dosage of 10 mg/kg twice daily (20 mg/kg/day). Any dosage increases above 10 mg/kg/day should take into account individual benefit and risk.

Financial factors

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resource because the population size is small.

Cannabidiol has a discount to the list price that is commercial in confidence. The list price of cannabidiol has been agreed with the Department of Health and Social Care but is considered confidential by the company until January 2020.

Highly specialised technology guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Acute kidney injury: prevention, detection and management NG148

This guideline covers preventing, detecting and managing acute kidney injury in children, young people and adults. It aims to improve assessment and detection by non-specialists, and specifies when people should be referred to specialist services. This will improve early recognition and treatment, and reduce the risk of complications in people with acute kidney injury.

This guideline includes new and updated recommendations on:

- preventing acute kidney injury in adults having iodine-based contrast media

It also includes recommendations on:

- assessing risk
- prevention
- detection
- identifying the causes of acute kidney injury
- management
- information and support for patients and carers

Menopause: diagnosis and management NG23 (update)

This guideline covers the diagnosis and management of menopause, including in women who have premature ovarian insufficiency. The guideline aims to improve the consistency of support and information provided to women in menopause.

In December 2019, in response to an MHRA safety alert on hormone replacement therapy (HRT) and the risk of breast cancer, NICE replaced the table in the recommendation on breast cancer risk with a link to the MHRA's advice on HRT risks and benefits. NICE will also update this recommendation as part of the planned update to the guideline.

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)

Balloon dilation for chronic eustachian tube dysfunction IPG665

This guidance replaces NICE interventional procedures guidance on balloon dilatation of the Eustachian tube (IPG409).

Recommendations

Evidence on the safety and efficacy of balloon dilation for eustachian tube dysfunction is adequate to support the use of this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit.

The condition

The eustachian tube is a narrow tube that connects the middle ear with the back of the nose. If it is blocked or does not open properly, there can be symptoms such as muffled hearing, pain, a feeling of fullness in the ear, tinnitus or dizziness. The eustachian tube typically becomes blocked after an upper respiratory tract infection or allergic rhinitis. It is usually a temporary problem that resolves spontaneously, but sometimes symptoms persist and treatment is necessary. Long-term eustachian tube dysfunction is associated with damage to the eardrum and middle-ear transformer mechanism.

Medical treatments include oral and nasal corticosteroids, decongestants and antihistamines. Autoinflation is a technique that reopens the eustachian tube by raising pressure in the nose. This can be achieved in several ways, including forced exhalation against a closed mouth and nose.

If eustachian tube dysfunction persists, a tympanostomy tube (a ventilation tube or grommet) may be inserted through a small incision in the tympanic membrane. These typically fall out after several months, and repeated tube insertions may be needed. Some tubes are designed to stay in place for longer, but these can become crusted, infected or obstructed. Tympanostomy tubes may result in a small permanent hole in the tympanic membrane; this is more common with long-lasting tubes.

The procedure

Balloon dilation of the eustachian tube is done using local or general anaesthesia. A balloon catheter is introduced into the eustachian tube via the nose, under transnasal endoscopic vision. Once the balloon is correctly positioned in the eustachian tube, it is filled with saline up to a pressure of about 10 to 12 bars. Pressure is maintained for about 2 minutes. The balloon is then emptied and removed.

The aim of the procedure is to widen the eustachian tube and improve its function.

Medical Technologies Guidance (MTGs)

gammaCore for cluster headache MTG46

Recommendations

Evidence **supports** the case for adopting gammaCore to treat cluster headache in the NHS. gammaCore reduces the frequency and intensity of cluster headache attacks and improves quality of life.

gammaCore is not effective in everyone with cluster headache. Treatment with gammaCore should only continue for people whose symptoms reduce in the first 3 months.

Cost modelling estimates that, in the first year of treatment, adding gammaCore to standard care is cost saving compared with standard care alone by an average of £450 per person. This cost saving:

- assumes that the first 3-month period of gammaCore use is offered by the company free of charge
- largely results from less use of subcutaneous sumatriptan.

The technology

gammaCore is a non-invasive vagus nerve stimulator used to treat and prevent cluster headaches. It is self-administered by the person or their carer. After applying conductive gel, gammaCore is held against the neck (over the cervical branch of the vagus nerve) and delivers a small electric current for about 2 minutes. This stimulation should be repeated 3 times. The device is small and portable.

gammaCore requires RFID (radio frequency identification) card activation which is renewed every 3 months (93 days). The RFID card activation allows gammaCore to deliver a maximum of 30 stimulations in each 24-hour period. Conductive gel is provided with each new RFID card. Additional gel can be provided at no extra cost.

gammaCore is currently the only technology that uses non-invasive stimulation of the vagus nerve to treat cluster headache.

Financial factors

Currently this technology is commissioned by NHS England through the Innovation and Technology Payment.

NICE does not expect this guidance to have a significant impact on resources; adding gammaCore to standard care treatment is deemed to not have a significant resource impact. This is based on the assumption that the company will offer a free 3-month trial, and where successful treatment results in a reduction in acute cluster headache incidents, there is less use of sumatriptan. Treatment with gammaCore should only continue for people whose symptoms reduce in the first 3 months. The resource impact assessment also assumes that there are no costs for gammaCore in people where treatment is not considered successful after 3 months.

Diagnostics Guidance (DGs)

None published this month.

NICE Quality Standards

Lung cancer in adults QS17 (update)

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

In December 2019, this quality standard was updated in response to an annual review, which identified changes in the areas for improvement for this topic.

Current NICE consultations

Title / link	End date of consultation
Selective internal radiation therapies for treating hepatocellular carcinoma ID1276	08/01/2020
Rezum for treating benign prostatic hyperplasia	08/01/2020
Human alpha1-proteinase inhibitor for treating emphysema ID856	09/01/2020
Blood transfusion	10/01/2020
Generalised anxiety disorder and panic disorder in adults: management	10/01/2020
Thyroid cancer: assessment and management	17/01/2020
Management of gout	21/01/2020
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	21/10/2020
Perioperative care in adults	24/01/2020
Trifluridine–tipiracil for treating metastatic gastric or gastro-oesophageal junction cancer after 2 or more therapies [ID1507]	24/01/2020
Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer ID1504	28/01/2020
Rehabilitation in adults with complex psychosis and related severe mental health conditions	05/02/2020