NICE Update Bulletin January 2017
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Hyperlinks to the relevant NICE web page are included, to activate link left click on your mouse. Details are also available from the NICE website (**http://www.nice.org.uk**)

Type	Guidance title and reference number

Technology Appraisals (TAs)	**Mepolizumab for treating severe refractory eosinophilic asthma TA431**
	
	Recommendations
	
	1.1 Mepolizumab, as an add-on to optimised standard therapy, is recommended as an option for treating severe refractory eosinophilic asthma in adults, only if:
	• the blood eosinophil count is 300 cells/microlitre or more in the previous 12 months and
	• the person has agreed to and followed the optimised standard treatment plan and
	  ○ has had 4 or more asthma 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 and
	• the company provides the drug with the discount agreed in the patient access scheme.
	
	1.2 At 12 months of treatment:
	• stop mepolizumab if the asthma has not responded adequately or
	• continue treatment if the asthma has responded adequately and assess response each year.
	
	An adequate response is defined as:
	• at least 50% fewer asthma exacerbations needing systemic corticosteroids in those people with 4 or more exacerbations in the previous 12 months or
	• a clinically significant reduction in continuous oral corticosteroid use while maintaining or improving asthma control.
	
	1.3 This guidance is not intended to affect the position of patients whose treatment with mepolizumab was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop.
	
	The technology
	
	Mepolizumab has a marketing authorisation in the UK as an 'add-on treatment for severe refractory eosinophilic asthma in adult patients'.
	
	Financial factors
	
	This technology is commissioned by NHS England. Mepolizumab is a long-term treatment add-on to optimised standard therapy. It should only be started in tertiary specialist commissioned centres. The need for continued therapy should be reviewed after 12 months of treatment, and response should be assessed each year.
	
	Sofosbuvir–velpatasvir for treating chronic hepatitis C TA430
	
	Recommendations
	
	1.1 Sofosbuvir–velpatasvir is recommended as an option for treating chronic hepatitis C in adults, as specified in table 1, only if the company provides the drug with the discount agreed in the simple discount agreement.

HCV genotype	Liver disease stage	Treatment	Recommendation according to treatment history	
			Untreated	Treated
1	With or without compensated cirrhosis	Sofosbuvir-velpatasvir	Recommended	
2	Without cirrhosis	Sofosbuvir-velpatasvir	Recommended only for people who cannot tolerate interferon or it is not suitable for them	Recommended
	Compensated cirrhosis	Sofosbuvir-velpatasvir	Recommended	
3	Without cirrhosis	Sofosbuvir-velpatasvir	Recommended	
	Compensated cirrhosis	Sofosbuvir-velpatasvir (with or without ribavirin)	Recommended	
4	With or without compensated cirrhosis	Sofosbuvir-velpatasvir	Recommended	
5	With or without compensated cirrhosis	Sofosbuvir-velpatasvir	Recommended	
6	With or without compensated cirrhosis	Sofosbuvir-velpatasvir	Recommended	
1-6	Decompensated cirrhosis	Sofosbuvir-velpatasvir (with ribavirin)	Recommended	

Abbreviation: HCV, hepatitis C virus.

Treated – the person's hepatitis C has not adequately responded to interferon-based treatment.

1.2 It is recommended that the decision to treat and prescribing decisions are made by multidisciplinary teams in the operational delivery networks put in place by NHS England, to prioritise treatment for people with the highest unmet clinical need.

1.3 This guidance is not intended to affect the position of patients whose treatment with sofosbuvir–velpatasvir was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop.

The technology

Sofosbuvir–velpatasvir has a marketing authorisation in the UK for treating chronic hepatitis C virus (HCV) infection in adults. This includes genotypes 1–6 HCV in people with or without compensated or decompensated cirrhosis.

Financial factors

This technology is commissioned by NHS England. The decision to treat and prescribing decisions are made by multidisciplinary teams in the operational delivery networks put in place by NHS England, to prioritise treatment for people with the highest unmet clinical need.

Ibrutinib for previously treated chronic lymphocytic leukaemia and untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation TA429

Recommendations

1.1 Ibrutinib alone is recommended within its marketing authorisation as an option for treating chronic lymphocytic leukaemia in adults:

- who have had at least 1 prior therapy or
- who have a 17p deletion or TP53 mutation, and in whom chemo-immunotherapy is unsuitable and
- only when the company provides ibrutinib with the discount agreed in the patient access scheme.

The technology

Ibrutinib 'as a single agent is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL)' and 'as a single agent or in combination with bendamustine and rituximab is indicated for the treatment of adult patients with CLL who have received at least one prior therapy'.

Financial factors

This technology is commissioned by NHS England. Ibrutinib is already funded by the NHS through the Cancer Drugs Fund (CDF) for people with relapsed or refractory CLL. Ibrutinib will now be available through routine commissioning, and there will be a resource impact for specialised commissioning.

Pembrolizumab for treating PD-L1-positive non-small-cell lung cancer after chemotherapy TA428

Recommendations

1.1 Pembrolizumab is recommended as an option for treating locally advanced or metastatic PD-L1-positive non-small-cell lung cancer in adults who have had at least one chemotherapy (and targeted treatment if they have an epidermal growth factor receptor [EGFR]- or anaplastic lymphoma kinase [ALK]-positive tumour), only if:

- pembrolizumab is stopped at 2 years of uninterrupted treatment and no documented disease progression, and
- the company provides pembrolizumab with the discount agreed in the patient access scheme revised in the context of this appraisal.

1.2 This guidance is not intended to affect the position of patients whose treatment with pembrolizumab was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop.

The technology

Pembrolizumab has a marketing authorisation for treating locally advanced or metastatic non-small-cell lung cancer (NSCLC) in adults whose tumours express PD-L1 (that is, with a tumour proportion score [TPS] ≥1%) and who have had at least 1 chemotherapy regimen. Patients with epidermal growth factor receptor (EGFR)- or anaplastic lymphoma kinase (ALK)-positive tumour mutations should also have had approved therapy for these mutations before having pembrolizumab.

Financial factors

This technology is commissioned by NHS England. Before the marketing authorisation was granted, pembrolizumab was available in the NHS through the early access to medicine scheme, because of this NHS England has indicated that this guidance will be implemented 30 days after final publication.

	Pomalidomide for multiple myeloma previously treated with lenalidomide and bortezomib TA427 This guidance replaces NICE technology appraisal guidance on pomalidomide for relapsed and refractory multiple myeloma previously treated with lenalidomide and bortezomib (TA338). **Recommendations** 1.1 Pomalidomide, in combination with low-dose dexamethasone, is recommended as an option for treating multiple myeloma in adults at third or subsequent relapse; that is, after 3 previous treatments including both lenalidomide and bortezomib, only when the company provides pomalidomide with the discount agreed in the patient access scheme. 1.2 This guidance is not intended to affect the position of patients whose treatment with pomalidomide was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop. **The technology** Pomalidomide 'in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least 2 prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy'. **Financial factors** This technology is commissioned by NHS England. This appraisal is a review of TA338, which did not recommend Pomalidomide for this indication. Pomalidomide was available through the Cancer Drugs Fund until November 2015.
Highly specialised technology guidance (HSTs)	**None published so far this month**
NICE Guidelines (NGs)	**Antimicrobial stewardship: changing risk-related behaviours in the general population (Joint NICE and Public Health England guideline) NG63** This guideline covers making people aware of how to correctly use antimicrobial medicines (including antibiotics) and the dangers associated with their overuse and misuse. It also includes measures to prevent and control infection that can stop people needing antimicrobials or spreading infection to others. It aims to change people's behaviour to reduce antimicrobial resistance and the spread of resistant microbes. This guideline includes recommendations on: • ensuring antimicrobial stewardship programmes are a local priority • providing information for the public about reducing inappropriate antimicrobial demand and use • providing information for the public about preventing and reducing the spread of infections • improving infection prevention knowledge and behaviour among children and young people • advising people on how to use antimicrobial medicines **Cerebral palsy in under 25s: assessment and management NG62** This guideline covers diagnosing, assessing and managing cerebral palsy in children and young people from birth up to their 25th birthday. It aims to make sure they get the care and treatment they need for the developmental and clinical comorbidities associated with cerebral palsy, so that they can be as active and independent as possible.

	This guideline includes recommendations on: • causes and recognition of cerebral palsy • multidisciplinary care and information and support • managing feeding and drooling problems • support with speech, language and communication • assessing and managing pain, discomfort, distress and sleep disturbances • information on other comorbidities, including mental health problems • transition to adults' services **Antenatal care for uncomplicated pregnancies CG62 (update)** This guideline covers the care that healthy women and their babies should be offered during pregnancy. It aims to ensure that pregnant women are offered regular check-ups, information and support. **January 2017:** A footnote was added to recommendation 1.6.2.2 linking to the related NICE diagnostics guidance on high-throughput non-invasive prenatal testing for fetal RHD genotype (DG25).
Interventional Procedures Guidance (IPGs)	**None published so far this month**
Medical Technologies Guidance	**None published so far this month**
Diagnostics Guidance	**Integrated multiplex PCR tests for identifying gastrointestinal pathogens in people with suspected gastroenteritis (xTAG Gastrointestinal Pathogen Panel, FilmArray GI Panel and Faecal Pathogens B assay) DG26** **Recommendations** 1.1 There is currently insufficient evidence to recommend the routine adoption in the NHS of the integrated multiplex polymerase chain reaction tests, xTAG Gastrointestinal Pathogen Panel, FilmArray GI Panel and Faecal Pathogens B assay, for identifying gastrointestinal pathogens in people with suspected gastroenteritis. 1.2 The tests show promise but further research is recommended on their effect on health outcomes and resource use in clinical practice.
NICE Quality Standards	**Learning disabilities: identifying and managing mental health problems QS142** This quality standard covers the prevention, assessment and management of mental health problems in people with learning disabilities in all settings (including health, social care, education, and forensic and criminal justice). It also covers family members, carers and care workers. It describes high-quality care in priority areas for improvement. It does not cover problem behaviours (challenging behaviour, aggressive behaviour, destructive behaviour, or self-injurious behaviour). They are covered by the NICE quality standard on learning disabilities: challenging behaviour. **Tuberculosis QS141** This quality standard covers preventing, identifying and managing latent and active tuberculosis (TB) in children, young people and adults. It describes high-quality care in priority areas for improvement. It does not cover areas of national policy, such as the UK Bacillus Calmette-Guérin (BCG) immunisation programme.

Current NICE consultations with links and end dates for stakeholders to contribute

Title / link	End date of consultation
Psoriatic arthritis - certolizumab pegol and secukinumab (after DMARDs) [ID579] : Appraisal consultation : 2	27/01/2017
Feverish illness in children : Surveillance consultation	30/01/2017
Urinary incontinence (update) and pelvic organ prolapse in women: management : Draft scope consultation	31/01/2017
Oral health in care homes and hospitals : Quality Standard consultation	03/02/2017
Liver disease : Quality Standard consultation	06/02/2017
Haematological cancers : Quality Standard consultation	07/02/2017
Cerebral palsy in children and young people : Topic engagement	08/02/2017
Specialist neonatal care : Draft scope consultation	09/02/2017
Hip fracture: management (standing committee update) : Addendum consultation	15/02/2017
Asthma management : Draft guidance consultation	16/02/2017
Renal stones : Draft scope consultation	17/02/2017
SecurAcath for securing percutaneous catheters : Draft guidance	20/02/2017
Violence and aggression : Quality Standard consultation	20/02/2017
Multimorbidity : Quality Standard consultation	20/02/2017

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