NHS Rotherham Clinical Commissioning Group
Framework of NICE Guidance
October 2016

NHS Rotherham Clinical Commissioning Group

Guideline No	Title	Summary	Implications & Action	Completed Actions
CG98	Jaundice in newborn babies under 28 days	This guideline covers diagnosing and treating jaundice, which is caused by increased levels of bilirubin in the blood, in newborn babies (neonates). It aims to help detect or prevent very high levels of bilirubin, which can be harmful if not treated. In October 2016, recommendation 1.4.9 was amended to clarify when intensified phototherapy should be used in relation to time since birth.	n/a	
CG155	Psychosis and schizophrenia in children and young people recognition and management	This guideline covers recognising and managing psychosis and schizophrenia in children and young people. It aims to improve early recognition of psychosis and schizophrenia so that children and young people can be offered the treatment and care they need to live with the condition. In October 2016, recommendation 1.3.19 and Table 1 were updated to remove reference to hip circumference percentile charts.	RDASH	
TA416	Osimertinib for treating locally advanced or metastatic EGFR T790M mutation –positive non-small-cell lung cancer	Osimertinib is recommended as an option for use within the Cancer Drugs Fund for treating locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer in adults whose disease has progressed only: •after first-line treatment with an EGFR tyrosine kinase inhibitor and •if the conditions in the managed access agreement for osimertinib are followed. 1.2 This guidance is not intended to affect the position of patients whose treatment with osimertinib 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 funding for this lies with NHSE	

Guideline No	Title	Summary	Implications & Action	Completed Actions
TA415	Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF alpha inhibitor	Certolizumab pegol, in combination with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other disease-modifying antirheumatic drugs (DMARDs) including at least 1 tumour necrosis factor-alpha (TNF-alpha) inhibitor, only if: •disease activity is severe and •rituximab is contraindicated or not tolerated and •the company provides certolizumab pegol with the agreed patient access scheme. 1.2 Certolizumab pegol, as monotherapy, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other DMARDs including at least 1 TNF-alpha inhibitor, only if: •disease activity is severe and •rituximab therapy cannot be given because methotrexate is contraindicated or not tolerated and •the company provides certolizumab pegol with the agreed patient access scheme. 1.3 Continue treatment only if there is at least a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months. After an initial response within 6 months, withdraw treatment if at least a moderate EULAR response is not maintained. 1.4 This guidance is not intended to affect the position of patients	This lies with the CCG and is monitored by the Blueteq.	

Guideline No	Title	Summary	Implications & Action	Completed Actions
		whose treatment with certolizumab pegol 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.		
TA414	Cobimetinib in combination with vemurafenib for treating unresectable or metastatic BRAF V600 mutation –positive melanoma	Cobimetinib in combination with vemurafenib is not recommended within its marketing authorisation for treating unresectable or metastatic melanoma in adults with a BRAF V600 mutation. 1.2 This guidance is not intended to affect the position of patients whose treatment with cobimetinib in combination with vemurafenib 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	Funding for this lies with NHSE	
TA413	Elbasvir-grazoprevir for treating chronic hepatitis C	Elbasvir–grazoprevir is recommended, within its marketing authorisation, as an option for treating genotype 1 or 4 chronic hepatitis C in adults, as specified in table 1, only if the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit. Table 1 Elbasvir–grazoprevir for treating chronic hepatitis C in adults Genotype Treatment and duration 1a Elbasvir–grazoprevir for 12 weeks. Consider elbasvir–grazoprevir plus ribavirin for 16 weeks in people with a baseline hepatitis C virus RNA level of more than 800,000 IU/ml or specific NS5A polymorphisms causing at least a 5‑fold reduction in activity of elbasvir.	Funding for this lies with NHSE	

Guideline No	Title	Summary	Implications & Action	Completed Actions
		1b Elbasvir–grazoprevir for 12 weeks. 4 Elbasvir–grazoprevir for 12 weeks. Consider elbasvir‑grazoprevir plus ribavirin for 16 weeks in people with a baseline hepatitis C virus RNA level of more than 800,000 IU/ml.		
QS135	Preterm labour and birth	Statement 1. Pregnant women at increased risk of preterm labour are given information about the potential signs and symptoms. Statement 2. Women who have had a previous preterm birth or mid-trimester loss and have a cervical length of less than 25 mm measured between 16+0 and 24+0 weeks of pregnancy are offered a choice of either prophylactic vaginal progesterone or prophylactic cervical cerclage. Statement 3. Women having a planned preterm birth are given information about the risks and potential outcomes. Statement 4. Women between 26+0 and 29+6 weeks of pregnancy who are in suspected preterm labour are offered tocolysis and maternal corticosteroids. Statement 5. Women between 30+0 and 33+6 weeks of pregnancy who are in diagnosed preterm labour, are having a planned preterm birth or have preterm prelabour rupture of membranes (P-PROM) are offered maternal corticosteroids. Statement 6. Women between 24+0 and 29+6 weeks of pregnancy who are in established preterm labour or having a planned preterm	F.A.O Midwives	

Guideline No	Title	Summary	Implications & Action	Completed Actions
		birth within 24 hours are offered magnesium sulfate.		
QS134	Coeliac disease	List of quality statements Statement 1. People at increased risk or with symptoms of coeliac disease are offered a serological test for coeliac disease. Statement 2. People with a positive serological test for coeliac disease are referred to a specialist and advised to continue with a gluten-containing diet until diagnosis is confirmed. Statement 3. People referred to a specialist who need an endoscopic intestinal biopsy to diagnose coeliac disease have it within 6 weeks of referral. Statement 4. People newly diagnosed with coeliac disease discuss how to follow a gluten-free diet with a healthcare professional with specialist knowledge of coeliac disease. Statement 5. People with coeliac disease are offered an annual review.	This is in line with CCG guidelines	
QS133	Children's attachment	List of quality statements Statement 1. Children and young people who may have attachment difficulties, and their parents or carers, have a comprehensive assessment before any intervention programme. Statement 2. Children and young people with attachment difficulties have an up-to-date education plan setting out how they will be supported in school. Statement 3. Parents and carers of preschool-age children with or at risk of attachment difficulties are offered a video feedback programme. Statement 4. Health and social care provider organisations provide		

Guideline No	Title	Summary	Implications & Action	Completed Actions
		training, education and support programmes for carers of school aged children and young people with attachment difficulties.		
MIB 85	Needle free arterial non-injectable connector	•The technology described in this briefing is the needle-free arterial non-injectable connector (NIC), which is connected to the sampling port of an arterial line and through which blood samples can be collected. •The innovative aspect is a safety feature that stops inappropriate injection into the arterial line. It may also help to prevent bacterial contamination of the arterial line and blood loss during sample collection. •The key points from the evidence summarised in this briefing are from a laboratory study showing that NIC prevents bacterial transfer from a syringe into a 3-way port; a user survey (n=258) showing that most users wanted to continue using the NIC after an implementation study finished; and a cost-effectiveness study, which concluded that using the NIC instead of standard connectors could save £285 per year in an average NHS trust. No evidence was available to show that using the NIC prevented inappropriate injections or blood loss in clinical practice, but the rarity of such events makes such a study unfeasible. •A key uncertainty around the evidence is whether there would be savings associated with using the NIC for NHS organisations that adopt this technology. •One single-use NIC costs £1.95 (including VAT).		
MIB84	Absorb Bioresorbable Vascular Scaffold for coronary artery disease	•The technology described in this briefing is the Absorb Bioresorbable Vascular Scaffold (BVS). It is a drug-eluting bioresorbable stent used for widening narrowed coronary arteries. •The innovative aspect is that over time it is resorbed in the artery, unlike metal stents.		

Guideline No	Title	Summary	Implications & Action	Completed Actions
		•The intended place in therapy would be for use in place of a metallic drug-eluting stent in people with coronary artery disease who are having angioplasty. •The key points from the evidence summarised in this briefing are from 4 good-quality meta-analyses and 1 randomised controlled trial. The evidence suggests that the risks of death, myocardial infarction and target lesion failure are similar for Absorb BVS, bare-metal stents and metallic drug-eluting stents at up to 12 months' follow-up. Stent thrombosis (definite or probable) was more frequent and medium-term in-device and in-segment lumen loss was greater with Absorb BVS than with some second-generation metallic drug-eluting stents. •Key uncertainties around the evidence are about longer-term outcomes associated with the Absorb BVS compared with metallic drug-eluting stents. NICE interventional procedures guidance recommends that bioresorbable stent implantation should only be used with special arrangements for clinical governance, consent and audit or research. •The Absorb BVS costs £2,200 (list price), excluding VAT. The cost of a standard drug-eluting stent varies but the average cost is estimated to be £529.		
MIB83	Woundcheck Protease Status for assessing elevated protease status in chronic wounds	•The technology described in this briefing is the Woundchek Protease Status point-of-care diagnostic test. It is designed to qualitatively assess protease activity (the presence of which may impair healing) in chronic wounds. •The potential innovative aspect is that it is currently the only commercially available test that can detect whether a wound has an elevated protease status. •The intended place in therapy would be for use by clinical staff		

Guideline No	Title	Summary	Implications & Action	Completed Actions
		treating chronic wounds, to aid decision-making on wound dressings. Protease modulating dressings could be chosen for wounds where elevated protease status is detected. The test could be used in any care setting. •The key points from the evidence summarised in this briefing are from 4 studies involving 412 people. One published prospective, non-comparative study showed that elevated protease activity (EPA), detected with the Woundchek Protease Status test, was significantly associated with dermal graft failure in diabetic foot ulcers. The Woundchek Protease Status test had a high positive predictive value (80%) for non-healing status in chronic wounds in a further study. A randomised controlled trial in people with diabetic foot ulcers found that more wounds healed or improved in a group tested for EPA and treated with protease modulating dressings where appropriate, compared with standard care. •Key uncertainties around the evidence are that it is limited in quality and quantity. The published prospective study was small (n=35) and the other publications lacked detail because 2 were conference presentations on small studies and 1 was a research poster. •The Woundchek Protease Status test costs £30 per test and does not need maintenance or calibration. Kits with control samples and additional reagent are also available.		
MIB82	UrgoStart for chronic wounds	•The technology described in this briefing is the UrgoStart wound dressing. It is used to treat chronic wounds such as diabetic foot ulcers, pressure ulcers or venous leg ulcers, as well as non-healing acute wounds. •The potential innovative aspect is that UrgoStart uses a technology lipido-colloid nano-oligosaccharide factor (TLC-NOSF), which is designed to inhibit protease activity, the presence of which may impair wound healing.		

Guideline No	Title	Summary	Implications & Action	Completed Actions
		•The intended place in therapy would be as an alternative to other advanced wound dressings in people with chronic wounds. •The key points from the evidence summarised in this briefing are from 2 randomised controlled trials (RCTs), 1 prospective case series and a poster presentation of a cross-sectional study. One RCT (n=117 patients) compared UrgoStart with an alternative protease modulating dressing. The other RCT (n=187 patients) compared UrgoStart with an identical dressing but without the NOSF protease modulating component. Both RCTs reported greater reductions in relative wound area when using UrgoStart dressings. •Key uncertainties around the evidence are that the available RCTs follow up patients for 8 and 12 weeks, which in most cases is not long enough to reach complete wound healing. No studies were carried out in community settings. •The cost per Urgostart dressing varies from £2.95 to £15.54 depending on the size and type, and some of these require additional absorbent dressings, retaining bandages or tape. Other dressings range from £1.00 to £7.07 for a similar range of sizes, depending on the type. •NICE has also published a medtech innovation briefing on the WoundChek Protease Status test for detecting elevated protease status.		
IPG566	Single-incision short sling mesh insertion for stress urinary incontinence in women	The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include lasting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but, if removal is needed because of complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in		

Guideline No	Title	Summary	Implications & Action	Completed Actions
		quality and quantity. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research. Patient selection should be done by a multidisciplinary team with experience in the assessment and management of women with stress urinary incontinence. 1.4 This procedure should only be done by clinicians with specific training in transobturator surgical techniques. Removal of a short sling mesh should only be done by people with expertise in this specialised surgery. 1.5 NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes**.**		
ESNM78	Pre-exposure prophylaxis of HIV in adults at high risk: Truvada (emtricitabine/tenofovir disoproxil)	This evidence summary reviewed 4 randomised trials of Truvada (emtricitabine/tenofovir disoproxil 200 mg/245 mg) for pre-exposure prophylaxis (PrEP) of HIV in either HIV-negative men or transgender women who have sex with men, or HIV-negative individuals in a heterosexual partnership with a person already infected with HIV. In these trials, Truvada reduced the relative risk of acquiring HIV infection by between 44% and 86% compared with placebo or no prophylaxis, which is equivalent to approximate numbers needed to treat of between 13 and 68 per year. In all trials, Truvada was given in addition to a comprehensive package of prevention services including HIV testing, risk-reduction counselling, condoms and sexually transmitted infection management. In addition to efficacy, issues relating to uptake, adherence, sexual behaviour, drug resistance, safety, prioritisation for prophylaxis and cost-effectiveness are also important to consider, especially at a population level. Regulatory status: A licence extension for the use of once-daily Truvada for PrEP was approved by the European Medicines Agency in August 2016. The aim of this evidence summary is to inform		

Guideline No	Title	Summary	Implications & Action	Completed Actions
		forward planning around the use of Truvada for PrEP within local health systems. In May 2016, BHIVA and BASHH published a position statement on PrEP in the UK, which recommends that PrEP be made available within a comprehensive HIV prevention package to: •men who have sex with men, trans men and trans women who are engaging in condomless anal sex •HIV-negative partners who are in serodiscordant heterosexual and same-sex relationships with a HIV-positive partner whose viral replication is not supressed •other heterosexuals considered to be at high risk.		