NHS Rotherham Clinical Commissioning Group
Framework of NICE Guidance
June 2016

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Guideline No	Title	Summary	Implications & Action	Completed Actions
TA392	Adalimumab for treating moderate to severe hidradenitis suppurativa	Adalimumab for treating active moderate to severe hidradenitis suppurativa in adults whose disease has not responded to conventional systemic therapy. Adalimumab is recommended, within its marketing authorisation, as an option for treating active moderate to severe hidradenitis suppurativa in adults whose disease has not responded to conventional systemic therapy. The drug is recommended only if the company provides it at the price agreed in the patient access scheme. Assess the response to adalimumab after 12 weeks of treatment, and only continue if there is clear evidence of response, defined as: •a reduction of 25% or more in the total abscess and inflammatory nodule count and •no increase in abscesses and draining fistulas.	This would be initiated within the dermatology department but would require CCG funding. Assessments are still to be made about what impact this will have in Rotherham.	
TA393	Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia	alirocumab (Praluent) for treating primary hypercholesterolaemia or mixed dyslipidaemia in adults. Alirocumab is recommended as an option for treating primary hypercholesterolaemia or mixed dyslipidaemia, only if: •Low‑density lipoprotein concentrations are persistently above the thresholds specified in table 1 despite maximal tolerated lipid‑lowering therapy. That is, either the maximum dose has been reached or further titration is limited by intolerance (as defined in NICE's guideline on familial hypercholesterolaemia: identification and management). •The company provides alirocumab with the discount agreed in the patient access scheme.	This guidance is not intended to affect the position of patients whose treatment with alirocumab 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. Secondary care initiation only	

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TA397	Belimumab for treating active autoantibody-positive systemic lupus erythematosus	belimumab (Benlysta) as an add-on treatment for active autoantibody-positive systemic lupus erythematosus in adults. Belimumab is recommended as an option as add-on treatment for active autoantibody-positive systemic lupus erythematosus in adults only if all of the following apply: •There is evidence for serological disease activity (defined as positive anti-double-stranded DNA and low complement) and a Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of greater than or equal to 10 despite standard treatment. •Treatment with belimumab is continued beyond 24 weeks only if the SELENA-SLEDAI score has improved by 4 points or more. •The company provides belimumab with the discount agreed in the patient access scheme. •Under the conditions for data collection, monitoring, patient eligibility and consent, ongoing treatment, cost to the NHS, and review by NICE as laid out in sections 5 and 6 of this document.	This will be monitored under the Blueteq system.	
QS12 update	Breast cancer	Statement 1. People with suspected breast cancer referred to specialist services are offered the triple diagnostic assessment in a single hospital visit. [new 2016] Statement 2. People with biopsy-proven invasive breast cancer or ductal carcinoma in situ (DCIS) are not offered a preoperative MRI scan unless there are specific clinical indications for its use. [new 2016] Statement 3. People with oestrogen receptor-positive (ER-positive), human epidermal growth factor receptor 2-negative		

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		(HER2-negative) and lymph node-negative early breast cancer who are at intermediate risk of distant recurrence are offered gene expression profiling with Oncotype DX. [new 2016] Statement 4. People with newly diagnosed invasive breast cancer and those with recurrent breast cancer (if clinically appropriate) have the oestrogen receptor (ER) and human epidermal growth factor receptor 2 (HER2) status of the tumour assessed. [2011, updated 2016] Statement 5. People with breast cancer who develop metastatic disease have their treatment and care managed by a multidisciplinary team. [2011, updated 2016] Statement 6. People with locally advanced, metastatic or distant recurrent breast cancer are assigned a key worker. [2011, updated 2016]		
QS122	Bronchiolitis in children	Statement 1: Children with bronchiolitis are not prescribed antibiotics to treat the infection. Statement 2. Parents and carers of children with bronchiolitis are informed that medication is not being used because the condition is usually self-limiting. Statement 3. Parents and carers of children with bronchiolitis are given key safety information about what to expect and when to be concerned if caring for the child at home. Statement 4 (placeholder). Admission avoidance and early supported discharge.	This reflects advice we would give clinicians currently. It will be reiterated in the winter planning communications.	
TA395	Ceritinib for previously	ceritinib (Zykadia) for treating advanced anaplastic lymphoma	Funding for this would lie	

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	treated anaplastic lymphoma kinase positive non small cell lung cancer	kinase positive non-small-cell lung cancer in adults who have had crizotinib. Ceritinib is recommended, within its marketing authorisation, as an option for treating advanced anaplastic lymphoma kinase positive non-small-cell lung cancer in adults who have previously had crizotinib. The drug is recommended only if the company provides it with the discount agreed in the patient access scheme	with NHSE	
ESNM75	Complicated intra-abdominal infections: ceftolozone/tazobactam	Ceftolozane/tazobactam may be an option for treating complicated intra-abdominal infections in some adults, when the pathogen is resistant to first-line empirical treatment options but susceptible to ceftolozane/tazobactam, or when first-line options are contraindicated. The acquisition cost of ceftolozane/tazobactam is more than that of many other intravenous antibiotics that are commonly used for complicated intra-abdominal infections.	Appropriate use of antibiotics is important to reduce the serious threat of antibiotic resistance and the risk of healthcare-associated infections such as C. difficile. Commissioners and local decision makers will need to determine where ceftolozane/tazobactam fits within local hospital antibiotic policies and guidelines for managing complicated intra-abdominal infections, taking the principles of antimicrobial stewardship into account.	
ESNM74	Complicated urinary tract infections:ceftolozone/tazobactam	Ceftolozane/tazobactam may be an option for treating acute pyelonephritis in some adults when the pathogen is resistant to first-line empirical treatment options but susceptible to ceftolozane/tazobactam, or when first-line options are contraindicated. Although licensed to treat complicated lower urinary tract infection in adults, clinical efficacy data in this group are limited. The acquisition cost of ceftozolane/tazobactam is more than that of many other IV antibiotics that are commonly	Commissioners and local decision makers will need to determine the place in therapy of ceftolozane/tazobactam within local hospital antibiotic policies for managing complicated urinary tract	

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		used for complicated urinary tract infection.	infections, taking the principles of antimicrobial stewardship into account.	
TA394	Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia	evolocumab (Repatha) for treating primary hypercholesterolaemia or mixed dyslipidaemia in adults. Evolocumab is recommended as an option for treating primary hypercholesterolaemia or mixed dyslipidaemia, only if: •The dosage is 140 mg every 2 weeks. •Low-density lipoprotein concentrations are persistently above the thresholds specified in table 1 despite maximal tolerated lipid-lowering therapy. That is, either the maximum dose has been reached, or further titration is limited by intolerance (as defined in NICE's guideline on familial hypercholesterolaemia). •The company provides evolocumab with the discount agreed in the patient access scheme.	This would be for secondary care specialist use only.	
MTG29	Greenlight XPS for treating benign prostatic hyperplasia	The case for adopting GreenLight XPS for treating benign prostatic hyperplasia is supported in non-high-risk patients. GreenLight XPS is at least as effective in these patients as transurethral resection of the prostate (TURP), but can more often be done as a day-case procedure, following appropriate service redesign. 1.2 There is currently insufficient high-quality, comparative evidence to support the routine adoption of GreenLight XPS in high-risk patients, that is those who: •have an increased risk of bleeding or	Cost modelling indicates that in non-high-risk patients, cost savings with GreenLight XPS compared with TURP are determined by the proportion of procedures done as day cases. Assuming a day-case procedure rate of 36%, and that the GreenLight XPS console is provided at no cost to the hospital (based on a contracted commitment to fibre usage), the estimated cost saving is £60 per	

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		•have prostates larger than 100 ml or •have urinary retention. NICE recommends that specialists collaborate in collecting and publishing data on the comparative effectiveness of GreenLight XPS for high‑risk patients to supplement the currently limited published evidence.	patient. NICE's resource impact report estimates that the annual cost saving for the NHS in England is around £2.3 million. In a plausible scenario of 70% of treatments being done as day cases, the cost saving may be up to £3.2 million.	
QS123	Home care for older people	Statement 1: Older people using home care services have a home care plan that identifies how their personal priorities and outcomes will be met. Statement 2. Older people using home care services have a home care plan that identifies how their home care provider will respond to missed or late visits. Statement 3. Older people using home care services receive care from a consistent team of home care workers who are familiar with their needs. Statement 4. Older people using home care services have visits of at least 30 minutes except when short visits for specific tasks or checks have been agreed as part of a wider package of support. Statement 5. Older people using home care services have a review of the outcomes of their home care plan within 6 weeks of starting to use the service and then at least annually. Statement 6. Home care providers have practice-based supervision discussions with home care workers at least every 3 months.	This will be communicated with adult nursing and continuing care	
IPG560	Microstructural scaffold (patch) insertion without autologous cell implantation for repairing	The evidence on microstructural scaffold insertion without autologous cell implantation for repairing symptomatic chondral knee defects raises no major safety concerns; however, current evidence on its efficacy is inadequate in both quality and quantity. Therefore, this procedure should	Clinicians wishing to do microstructural scaffold insertion without autologous cell implantation for repairing	

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	symptomatic chondral knee defects	only be used with special arrangements for clinical governance, consent, and audit or research.	symptomatic chondral knee defects should: •Inform the clinical governance leads in their NHS trusts. •Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended. •Audit and review clinical outcomes of all patients having microstructural scaffold insertion without autologous cell implantation for repairing symptomatic chondral knee defects (see section 7.1).	
ESNM77	Moderate to severe acute post-operative pain:fentanyl transdermal system	The fentanyl transdermal system, Ionsys, is a patient-controlled analgesia (PCA) system that delivers fentanyl in a non-invasive way across the skin using iontophoresis. It is licensed for the management of acute moderate to severe post-operative pain in adults. The fentanyl transdermal system has comparable efficacy to IV morphine PCA. Its adverse event profile is as expected for an opioid used in post-operative pain, and is similar to that of IV morphine PCA. In randomised controlled trials, the fentanyl transdermal system had better user satisfaction than IV morphine PCA, mainly because of improved mobilisation, and more favourable ease of care scores reported by nurses and physiotherapists. However, the clinical significance of these		

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		differences is unclear. Regulatory status: Ionsys was launched in February 2016 for the management of acute moderate to severe post-operative pain in adults. It is for hospital use only.		
MIB68	S-Cath System for suprapubic catheterisation	The S-Cath System is intended for use in people for whom a suprapubic catheter is indicated, and differs from conventional suprapubic catheters because a guidewire (the Seldinger technique) is used for improved placement. The available evidence is of limited quantity and quality. Three non-comparative studies suggest that suprapubic catheterisation using the S-Cath System is a safe procedure when carried out under appropriate conditions in a dedicated outpatient clinic, with low complication rates. In 1 of these studies, suprapubic catheterisation was moved from an inpatient to an outpatient setting. This was shown to be cost saving, however it is unclear if the S-Cath System was a significant factor in these savings. The S-Cath System costs between £36.39 and £41.92 (excluding VAT and carriage) depending on catheter size and type. Catheters should be replaced at least every 29 days. A Rapid Response Report by the National Patient Safety Agency (2009) recommends that ultrasound is used wherever possible to visualise the bladder and guide the insertion of suprapubic catheters. Ultrasound machines should be available in the relevant areas and staff trained in their use.		
MIB69	Cellvizio confocal endomicroscopy system for characterising pancreatic cysts	Cellvizio is a confocal laser endomicroscopy (CLE) system with a fibre-optic probe for real-time imaging of tissues. It is designed for use as an adjunct to the standard endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) procedure, to characterise pancreatic cysts and provide additional information to help guide therapeutic decisions	The main capital component of the Cellvizio system costs £79,000 with installation, commissioning and initial training costs of £2,145. Each fibre-optic miniprobe (AQ-Flex 19) can be used up to 10 times and costs £4,000. All costs are excluding VAT.	

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MIB70	Mobi-C for cervical disc replacement	Mobi-C is a prosthetic device used for 1- or 2-level cervical disc replacement. It is designed for people with cervical disc degeneration. systematic review concluded that Mobi-C is non inferior to anterior cervical discectomy and fusion (ACDF). The studies found that Mobi-C (at 1 or 2 levels) was more effective than ACDF for overall success and for reducing limitations of daily activity as a result of neck pain, and allowed a greater range of motion with less adjacent segment degeneration and less need for subsequent surgery. Each Mobi-C prosthesis costs £1,750 (excluding VAT).		
TA396	Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma	trametinib (Mekinist) with dabrafenib (Tafinlar) for adults with unresectable or metastatic melanoma that has a BRAF V600 mutation. Trametinib in combination with dabrafenib is recommended, within its marketing authorisation, as an option for treating unresectable or metastatic melanoma in adults with a BRAF V600 mutation only when the company provides trametinib and dabrafenib with the discounts agreed in the patient access schemes	Funding for this would lie with NHSE	
IPG561	Transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting	This involves reversing blood flow away from the brain and filtering the blood to remove any debris. Current evidence on the safety of transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting shows well-documented risks. The evidence on efficacy is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Patient selection should be carried out by a multidisciplinary team, which should include an interventional radiologist or a neuroradiologist, a vascular surgeon and a physician with a specialist interest in stroke. This procedure should only be carried out by clinicians with specific training and expertise in the technique who regularly perform complex endovascular interventions.		
IPG562	Ultrasound-guided percutaneous radiofrequency ablation for	This involves using heat energy to destroy tissue in the nodules. Current evidence on the safety and efficacy of ultrasound-guided percutaneous radiofrequency ablation for benign thyroid nodules is		

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	benign thyroid nodules	adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.		
ESNM76	Visual Impairment due to myopic choroidal neovascularisation:aflibercept	Intravitreal aflibercept is a vascular endothelial growth factor (VEGF) inhibitor that is already licensed for several ophthalmic indications. Aflibercept is the second VEGF inhibitor licensed in the UK for the treatment of myopic CNV. The other VEGF inhibitor licensed for this condition, ranibizumab, is recommended as an option in the NICE technology appraisal guidance on ranibizumab for treating choroidal neovascularisation associated with pathological myopia (TA298). Aflibercept 40 mg/ml solution for injection costs £816 per vial, compared with £742 for a vial of ranibizumab 10 mg/ml solution (costs taken from MIMS, April 2016), although both drugs are discounted based on a confidential patient access scheme.	Prescribers and local decision makers need to consider the available evidence on efficacy and safety, as well as cost and individual patient factors, when making decisions about using aflibercept for the treatment of myopic CNV. There are no RCTs comparing aflibercept with other active treatments.	