NEL Commissioning Support Unit

Anglia

Therapeutics Advisory Group

Recommendations from the Norfolk & Waveney Therapeutics Advisory Group (TAG) and related *Commissioning Decisions* by the CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) – January 2016

Recommending Body	Drug	Indication for Use	TAG Clinical Recommendation	*N&W CCGs - D&TCG Commissioning Decision / Recommendation*
NICE TA 363 (November 2015) Recommended by NICE as an option for treating chronic hepatitis C in adults, as specified in the guidance.	Ledipasvir–sofosbuvir (*Harvoni®*)	**For treating chronic hepatitis C as follows:** **No previous treatment of hepatitis C:** *Type 1 hepatitis C, without cirrhosis - 8 weeks' treatment* *Type 1 or 4 hepatitis C, with cirrhosis - 12 weeks' treatment* Inadequate response to previous treatment of hepatitis C: *Type 1 or 4 hepatitis C, without cirrhosis - 12 weeks' treatment* *Type 1 or 4 hepatitis, with cirrhosis - 12 weeks' treatment, only if low risk of disease progression*	The TAG noted NICE TA 363 (November 2015) and recommended a traffic light classification of **Red (Hospital/Specialist only)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.*
NICE TA 364 (November 2015) Recommended by NICE as an option for treatment of adults with chronic hepatitis C (with sofosbuvir or peginterferon alfa, and with ribavirin), depending on the level of fibrosis, and as specified in the guidance.	Daclatasvir (*Daklinza®)*	**For treating chronic hepatitis C as follows:** **No previous treatment of hepatitis C:** *Type 1 hepatitis, without cirrhosis - Daclatasvir plus sofosbuvir only for people with significant fibrosis - 12 weeks* *Type 4 hepatitis - Daclatasvir plus peginterferon alfa and ribavirin, only for significant fibrosis or cirrhosis - 24 weeks* **Previous treatment of hepatitis C:** *Type 1 or 4 hepatitis without cirrhosis - Daclatasvir plus sofosbuvir, only for significant fibrosis - 12 weeks* *Type 4 hepatitis - Daclatasvir plus peginterferon alfa and ribavirin, only for people with significant fibrosis or cirrhosis – 24 weeks*		*Noted by the D&TCG.*

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		If unable to have interferon: *Types 1, 3 or 4 hepatitis without cirrhosis - Daclatasvir plus sofosbuvir, only for people with significant fibrosis - 12 weeks* *Types 1 or 4 hepatitis with cirrhosis - Daclatasvir plus sofosbuvir, with or without ribavirin - 24 weeks* *Type 3 hepatitis, with cirrhosis - Daclatasvir plus sofosbuvir and ribavirin - 24 weeks*	TAG noted **NICE TA 364 (November 2015)** and recommended a traffic light classification of **Red (Hospital/Specialist only)** for this SCG-commissioning responsibility treatment.	
NICE TA 365 (November 2015) Recommended by NICE as an option for treating genotype 1 or 4 chronic hepatitis C in adults, as specified within the guidance, and only if the company provides ombitasvir–paritaprevir–ritonavir and dasabuvir at the same price or lower than that agreed with the NHS Commercial Medicines Unit.	Ombitasvir–paritaprevir–ritonavir (*Viekirax*®) with or without dasabuvir (*Exviera*®)	**For treating chronic hepatitis C as follows:** ***Type 1a hepatitis, without cirrhosis*** *- Ombitasvir–paritaprevir–ritonavir with dasabuvir and ribavirin - 12 weeks* ***Type 1a hepatitis, with cirrhosis*** *- Ombitasvir–paritaprevir–ritonavir with dasabuvir and ribavirin - 24 weeks* ***Type 1b hepatitis, without cirrhosis*** *- Ombitasvir–paritaprevir–ritonavir with dasabuvir - 12 weeks* ***Type 1b, with cirrhosis*** *- Ombitasvir–paritaprevir–ritonavir with dasabuvir and ribavirin - 12 weeks* ***Type 4 hepatitis, without cirrhosis*** *- Ombitasvir–paritaprevir–ritonavir with ribavirin - 12 weeks* ***Type 4 hepatitis, with cirrhosis*** *- Ombitasvir–paritaprevir–ritonavir with ribavirin - 24 weeks* TAG noted **NICE TA 365 (November 2015)** and recommended a traffic light classification of **Red (Hospital/Specialist only)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.*

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NICE TA 366 (November 2015) Recommended by NICE as an option for treating advanced (unresectable or metastatic) melanoma that has not been previously treated with ipilimumab, in adults, and only if the company provides pembrolizumab with the discount agreed in the patient access scheme.	Pembrolizumab (*Keytruda*®)	Treatment of advanced (unresectable or metastatic) melanoma in adults not previously treated with ipilimumab	TAG noted **NICE TA 366 (November 2015)** and recommended a traffic light classification of **Red (Hospital/Specialist only)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.*
NICE TA 367 (November 2015) *Recommended by NICE as a possible treatment option as per specified criteria.*	Vortioxetine (*Brintellix*®)	Treatment of major depressive episodes in adults having a first or recurrent major depressive episode, if the current episode has not responded to two antidepressants.	Discussions took place around the need for a business case for this treatment and the committee confirmed that in order for there to be equity amongst the Trusts, and to ensure that due process is followed, then both a business case and proposed treatment pathway were needed. Details of the most cost-effective treatment options should be included in the business case along with potential patient numbers. The TAG noted **NICE TA 367 (November 2015)** and recommended a classification of **Double Red (Not recommended for routine use/not commissioned)** for this CCG-commissioning responsibility treatment pending the submission of a business application and treatment pathway by the local Trust.	*The TAG's recommendations were noted and supported by the D&TCG.* ***Not commissioned** pending consideration of a business application and treatment pathway by the local provider Trust.*

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NICE TA 368 (November 2015) ***Not** recommended by NICE*	Apremilast (*Otezla*®)	Treatment of moderate to severe plaque psoriasis that has not responded to systemic therapy, or where systemic therapy is contraindicated or not tolerated.	The TAG noted **NICE TA 368 (November 2015)** and recommended a classification of **Double Red (Not recommended for routine use/not commissioned)** for this CCG-commissioning responsibility treatment.	*The TAG's recommendation was noted and supported by the D&TCG.* ***The treatment is Not Commissioned.***
NICE TA 369 (December 2015) Recommended by NICE as an option.	Ciclosporin (*Ikervis*®)	Treatment of severe keratitis in adult patients with dry eye disease that has not improved despite treatment with tear substitutes	NNUH have been using ciclosporin eye drops ahead of NICE. It was agreed that this is a treatment which needs to be considered by the TAG and NNUH would update their existing business case and bring it back to the next meeting for consideration. TAG noted **NICE TA 369 (December 2015)** and recommended a traffic light classification of **Red (Hospital/Specialist only)** for the CCG-commissioning responsibility treatment.	*The D&TCG noted the TAG's recommendation and decided that the treatment is **Not Commissioned** pending submission of a business application and treatment pathway by the local provider Trust.* *Traffic light classification to be revised to* **Double Red (Not recommended for routine use/not commissioned)**.
NICE TA 370 (December 2015) Recommended by NICE as an option	Bortezomib (*Velcade*®)	Treatment of previously untreated mantle cell lymphoma in adults for whom haematopoietic stem cell transplantation is unsuitable	TAG noted **NICE TA 370 (December 2015)** and recommended a traffic light classification of **Red (Hospital/Specialist only)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.*

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NICE TA 371 (December 2015) **Not** recommended by NICE	Trastuzumab emtansine (*Kadcyla*®)	Treatment of HER2-positive, unresectable locally advanced or metastatic breast cancer, after treatment with trastuzumab and a taxane (paclitaxel or docetaxel)	The TAG noted **NICE TA 371 (December 2015)** and recommended a classification of **Double Red (Not recommended for routine use/not commissioned)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.*
NICE TA 372 (December 2015) **Not** recommended by NICE	Apremilast (*Otezla*®) (alone or in combination with disease modifying anti-rheumatic drug (DMARD) therapy)	Treatment of active psoriatic arthritis in adults with active psoriatic arthritis that has not responded to prior DMARD therapy, or such therapy is not tolerated.	The TAG noted **NICE TA 372 (December 2015)** and recommended a classification of **Double Red (Not recommended for routine use/not commissioned)** for this CCG-commissioning responsibility treatment.	*The TAG's recommendation was noted and supported by the D&TCG.* ***The treatment is Not Commissioned.***
NICE TA 373 (December 2015) Recommended by NICE as an option. (There is currently a treatment pathway for the use of the drugs locally for adult JIA patients in line with interim guidance from NHS England for children and young adults with JIA.)	Abatacept (*Orencia*®), adalimumab (*Humira*®), etanercept (*Enbrel*®) and tocilizumab (*RoActemra*®) for treating juvenile idiopathic arthritis	Recommended as possible treatments for children and young people with polyarticular juvenile idiopathic arthritis. Adalimumab and etanercept are recommended as options for enthesitis-related juvenile idiopathic arthritis. Etanercept is recommended as a possible option for psoriatic juvenile idiopathic arthritis.	The TAG noted that NICE TA 373 differed from NHS England's interim policy (July 2015) regarding the clinical conditions covered and the recommended treatments and recommended waiting until NHS England published its final policy document post NICE TA 373 before making any changes to what is commissioned locally. The TAG noted **NICE TA 373 (December 2015)** and recommended a classification of **Red (Hospital/Specialist only)** for these SCG-commissioning responsibility treatments.	*Noted by the D&TCG.*

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NICE TA 374 (December 2015) Recommended by NICE as an option.	Erlotinib (*Tarceva*®) and gefitinib (*Iressa*®)	Treatment of locally advanced or metastatic non-small-cell lung cancer (NSCLC) that has progressed after prior non-targeted chemotherapy because of delayed confirmation of epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation status, if • the cancer tests positive for the EGFR TK mutation or • it is not known if the cancer is EGFR TK mutation positive because of problems with the test, and ○ the cancer is very likely to be EGFR TK mutation positive ○ it responds to the first 2 cycles of treatment with erlotinib • Erlotinib is not recommended for treating locally advanced or metastatic NSCLC that doesn't test positive for the EGFR TK mutation. • Gefitinib is not recommended for treating NSCLC that has progressed after chemotherapy.	The TAG noted **NICE TA 374 (December 2015)** and recommended a classification of **Red (Hospital/Specialist only)** for the SCG-commissioning responsibility treatments recommended by NICE. **Double Red (Not recommended for routine use/not commissioned)** entries would also be made on the TAG database for the treatments not recommended by NICE.	*Noted by the D&TCG.*

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NICE Highly Specialised Technology Appraisal HST2 (December 2015) Recommended by NICE as an only if the managed patient access agreement is signed up to. This includes rules for starting and stopping treatment, and for assessing how well it works. NICE will take the information about how well the treatment works into account when the guidance on elosulfase alfa is reviewed.	Elosulfase alfa (*Vimizim*®)	Treatment of mucopolysaccharidosis type Iva	The TAG previously noted NHS England commissioning policy E06/P/b (E06X02) (July 2015) which stated that the treatment was not routinely commissioned pending publication of the NICE Highly Specialised Technology Appraisal. i.e. Currently **Double Red / Not routinely commissioned by NHSE**. The TAG noted **NICE Highly Specialised Technology Appraisal HST2 (December 2015)** for this SCG-commissioning responsibility treatment and will await further commissioning information from NHS England.	*Noted by the D&TCG.*
NG 22 (November 2015) **Older people with social care needs and multiple long-term conditions** This guideline covers planning and delivering social care and support for older people who have multiple long-term conditions. It promotes an integrated and person-centred approach to delivering effective health and social care services.	No specific drug treatments mentioned.	**Includes recommendations on:** • Identifying and assessing social care needs • Care planning, including the role of the named care coordinator • Supporting carers • Integrating health and social care planning • Delivering care • Preventing social isolation • Training health and social care practitioners	The TAG noted **NG 22 (November 2015)**.	*Noted by the D&TCG.*

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NG 23 (November 2015) **Menopause: diagnosis and management** 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.	Various general drug treatment-related recommendations throughout the guidance	**Includes recommendations on:** • Individualised care • Diagnosis of perimenopause and menopause • Information and advice • Managing short-term menopausal symptoms • Long-term benefits and risks of hormone replacement therapy • Diagnosing and managing premature ovarian insufficiency	The TAG noted **NG 23 (November 2015)**.	*Noted by the D&TCG.*
NG 24 (November 2015) Blood transfusion This guideline covers the assessment for and management of blood transfusions in adults, young people and children over 1 year old. It covers the general principles of blood transfusion, but does not make recommendations relating to specific conditions.	Includes advice on alternatives to blood transfusion for patients having surgery	**Includes recommendations on:** • alternatives to transfusion for patients having surgery • thresholds, targets and doses for red blood cells, platelets, fresh frozen plasma, cryoprecipitate, and prothrombin complex concentrate • patient safety • patient information	The TAG noted **NG 24 (November 2015)**.	*Noted by the D&TCG.*
NG 25 (November 2015) **Preterm labour and birth** This guideline covers the care of women at increased risk of or with symptoms and signs of preterm labour (before 37 weeks) and women having a planned preterm	Various, including those related to prevention of infection, delaying labour	**Includes recommendations on:** • diagnosing, and caring for women with, preterm pre-labour rupture of membranes (P-PROM) • diagnosing preterm labour • preventing or delaying	The TAG noted **NG 25 (November 2015)**.	*Noted by the D&TCG.*

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birth. It aims to reduce the risks of preterm birth for the baby and describes treatments to prevent or delay early labour and birth.		preterm birth • treatments aimed at lowering the risk of health problems for the baby • foetal monitoring for women in pre-term labour • mode of birth and clamping the cord • information and support		
NG 26 (November 2015) **Children's attachment: attachment in children and young people who are adopted from care, in care or at high risk of going into care** This guideline covers the identification, assessment and treatment of attachment difficulties in children and young people up to age 18 who are adopted from care, in special guardianship, looked after by local authorities in foster homes (including kinship foster care), residential units and other accommodation, or on the edge of care. It aims to address the emotional and psychological needs of children and young people in these situations, including those resulting from maltreatment.	No specific drug treatments mentioned.	**Includes recommendations on:** • principles of care • supporting children and young people with attachment difficulties • assessing attachment difficulties • interventions for attachment difficulties in children and young people on the edge of care • interventions for attachment difficulties in children and young people in the care system, subject to special guardianship orders and adopted from care • interventions for attachment difficulties in children and young people in residential care	The TAG noted **NG 26 (November 2015)**.	*Noted by the D&TCG.*

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NG 27 (November 2015) **Transition between inpatient hospital settings and community or care home settings for adults with social care needs** This guideline covers the transition between inpatient hospital settings and community or care homes for adults with social care needs. It aims to improve people's experience of admission to, and discharge from, hospital by better coordination of health and social care services.	No specific drug treatments mentioned.	**Includes recommendations on:** • person-centred care and communication and information sharing • before admission to hospital including developing a care plan and explaining what type of care the person might receive • admission to hospital including the establishment of a hospital-based multi-disciplinary team • during hospital stay including recording medicines and assessments and regularly reviewing and updating the person's progress towards discharge • discharge from hospital including the role of the discharge coordinator • supporting infrastructure • training and development for people involved in the hospital discharge process.	The TAG noted **NG 27 (November 2015)**	*Noted by the D&TCG.*
NG 28 (December 2015) Type 2 diabetes in adults: management This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). It focuses on patient education,	Various	**Includes new recommendations on:** • individualised care • managing blood glucose levels: - HbA1c measurement and	The TAG noted **NG 28 (December 2015)**. The TAG was advised that NG 28 had been added to the agenda for the	*Noted by the D&TCG.* *The committee noted in particular the changes to advice regarding blood glucose*

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dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications. ***Also*** NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes **-** *link* *Plus* Patient Decision Aid - Type 2 diabetes in adults: *controlling your blood glucose by taking a second medicine – what are your options?*		targets - self-monitoring of blood glucose - drug treatment • antiplatelet therapy • managing complications	next NIDM meeting and the local treatment guidelines would be updated to reflect this guidance.	*monitoring and HbA1c targets in the frail and elderly.*
NG 29 (December 2015) **Intravenous fluid therapy in children and young people under 16 years in hospital** This guideline aims to improve patient safety for children and young people having IV fluid therapy in hospital.	Those related to fluid and electrolyte replacement and balance	**Includes recommendations on:** • principles and protocols for intravenous fluid therapy • assessment and monitoring • fluid resuscitation • routine maintenance • replacement and redistribution • managing hypernatraemia and hyponatraemia that develops during intravenous fluid therapy • training and education	The TAG noted **NG 29 (December 2015)**.	*Noted by the D&TCG.*
NG 30 (December 2015) Oral health promotion: general dental practice This guideline covers how general dental practice teams can convey	Fluoride supplements	**The recommendations cover:** • oral health advice given by dentists and dental care professionals • how dentists and dental care	The TAG noted **NG 30 (December 2015)**.	*Noted by the D&TCG.*

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advice about: • oral hygiene and the use of fluoride • diet, smoking, smokeless tobacco and alcohol intake.		professionals can adopt a patient-centred approach		
NG 31 (December 2015) Care of dying adults in the last days of life This guideline aims to improve end of life care for people in their last days of life by communicating respectfully and involving them, and the people important to them, in decisions and by maintaining their comfort and dignity. It covers how to manage common symptoms without causing unacceptable side effects and maintain hydration in the last days of life.	Various	**Includes recommendations on:** • recognising when people are entering the last few days of life • communicating and shared decision-making • clinically assisted hydration • medicines for managing pain, breathlessness, nausea and vomiting, anxiety, delirium, agitation, and noisy respiratory secretions • anticipatory prescribing	The TAG noted **NG 31 (December 2015)**.	*Noted by the D&TCG.*
NG 32 (December 2015) Older people: independence and mental wellbeing This guideline covers interventions to maintain and improve the mental wellbeing and independence of people aged 65 or older and how to identify those most at risk of a decline.	No specific drug treatments mentioned.	**The guideline includes recommendations on:** • principles of good practice • group-based activities • one-to-one activities • volunteering • identifying people most at risk of a decline	The TAG noted **NG 32 (December 2015)**.	*Noted by the D&TCG.*

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NHS England **Interim Clinical Commissioning Policy Reference: D12X02 (Nov 2015)** NHS England will routinely commission in accordance with the criteria outlined in this document on an interim basis until the details of the Sycamore trial are published.	Adalimumab (*Humira*®)	Treatment of children with Severe Refractory Uveitis with onset in childhood (age 2 or more up to 18 or less)	The TAG was advised that the trial was stopped early because it showed that the treatment is effective. NHS England has been provided with the trial data ahead of publishing and has found it so compelling that they have agreed to fund. The TAG otherwise noted Policy D12x02 and recommended a classification of **Red (Hospital/Specialist only)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.*
Clinical Commissioning Policy: - Reference: NHS England D12/P/b (Nov 2015) *Not* routinely funded by NHS England.	Infliximab (*Remicade*®)	As Anti-TNF Alpha Treatment Option for Paediatric Patients with Severe Refractory Uveitis	The TAG noted Policy D12/P/b and recommended a classification of **Double Red (Not routinely commissioned)** for this SCG-commissioning responsibility treatment.	*Noted by the D&TCG.*
East of England Priorities Advisory Committee (PAC): This medication has recently received approval for the EAMS scheme and will have implications for primary and secondary care prescribing in 2016. EoE PAC has recommended waiting on NICE guidance – due May 2016 and does not support early	Sacubitril / Valsartan (*Entresto*®) - Novartis	Treatment of symptomatic chronic heart failure with reduced ejection fraction in adults.	The TAG noted that through EAMS, the drug is initially made available free of charge to the NHS. Novartis will manage all requests from specialist heart failure services and provide NHS England and CCGs with a regular update detailing the participating centres and the number of patients entered. The TAG noted and supported the EoE PAC's recommendation to wait	*The D&TCG noted and supported the TAG's recommendations and confirmed* Sacubitril / Valsartan (*Entresto*®) for treatment of symptomatic chronic heart failure with reduced ejection fraction in adults ***is not supported or***

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provision of this treatment via the NHS England Early Access to Medicines Scheme (EAMS).			on the publication of NICE guidance before this treatment is used within the NHS. The TAG had concerns that provision via EAMS would produce a cohort of patients already receiving treatment who may not fit any criteria later specified by NICE. The TAG recommended a classification of **Double Red (Not routinely commissioned)** for this CCG-commissioning responsibility treatment.	***commissioned ahead of NICE guidance – i.e.* Double Red (Not routinely commissioned)**. *Usual processes for commissioning the treatment would be followed if NICE publishes a positive technology appraisal for its use.*
East of England Priorities Advisory Committee (PAC): **Guidance Statement Summary (developed leading up to publication in April 2015)** Rifaximin (550mg twice a day) is recommended as an option for second line add on therapy • when lactulose alone has proved ineffective. • First line management of HE with rifaximin is NOT recommended. • The use of rifaximin 200mg for any other indication is NOT recommended. (**NICE TA 337 (March 2015)** was published after the PAC guidance was finalised)	Rifaximin (*Targaxan*®)	Prevention of episodes of overt hepatic encephalopathy (HE)	Currently classified as Red (Hospital only) following D&TCG decision to overturn a previous TAG recommendation of Amber (option for shared care prescribing) (July 2012). Locally commissioned as an In-tariff treatment. The TAG noted that the PAC guidance document states that "*Rifaximin is not included in the PbR Tariff and will need to be funded and commissioned by CCGs. Rifaximin is listed as category C in the PPA Drug Tariff.*" The TAG is seeking advice on the current PbR status of this treatment. Local Acute Trusts are currently working on a proposed Shared Care Agreement for use of this treatment.	*Noted by the D&TCG.* *Current* Red (Hospital only) *classification to be maintained in the interim.*

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Therapeutics Advisory Group: **QEH Application:**	Lidocaine 5% medicated plasters (*Versatis*®)	Treatment of localised neuropathic pain when first line systemic therapies are ineffective or not tolerated	The TAG recommended that use of lidocaine 5% medicated plasters (*Versatis*®) in patients with localised neuropathic pain when first line systemic therapies are ineffective or not tolerated is classified as Green (GP prescribable following Consultant/Specialist initiation), with initiation by the Consultant within the Pain Clinic (i.e. the Consultant to give the first prescription) and effectiveness assessed before treatment is continued. An audit of usage should be carried out after 6 months and reported back to the CCGs.	*The D&TCG was concerned about the relative lack of evidence for this expensive product and the potential for inappropriate use outside the terms of agreed criteria and a treatment pathway. The committee supported the TAG's recommendation that the treatment should be initiated by the specialist within the pain clinic (first month's supply provided) and its effectiveness assessed before GPs are asked to prescribe. The D&TCG also recommended that the neuropathic pain treatment pathway (within the N&W Analgesic Formulary) be clarified to indicate that ineffective treatments are stopped before moving to the next option, to avoid unnecessary polypharmacy.*

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Therapeutics Advisory Group: **NNUH Application:** Business application and proposed Treatment Pathway submitted with respect to NICE TA 329.	Infliximab (*Inflectra*®), Golimumab (*Simponi*®), Adalimumab (*Humira*®)	Anti-TNF therapy for induction of remission with or without steroids, in patients with ulcerative colitis with moderate-severe disease unresponsive to or dependent upon steroids despite appropriate trials of thiopurine preparations as per NICE TA 329.	For patients who have a secondary loss of response, a second anti-TNF is being requested. The application proposes that it is more cost-effective to give a second anti-TNF agent rather than move on to vedolizumab. The TAG supported the NNUH's application and proposed treatment pathway and recommended a traffic light classification of Red (Hospital only) for these CCG-commissioning responsibility treatments.	*The D&TCG noted the discussion from the TAG meeting and requested clarification regarding the application and the proposed treatment pathway with respect to NICE guidance.* *To be reconsidered at the February 2016 D&TCG meeting before a commissioning decision is finalised.*
Therapeutics Advisory Group: **NNUH Applications and proposed treatment pathway:** Gastroenterology and Oncology / Palliative Care Business applications and suggested treatment pathway from the NNUH Palliative Care and Gastroenterology departments submitted with respect to NICE TA 345	Naloxegol (*Moventig*®)	As an option for treating opioid-induced constipation in adults whose constipation has not adequately responded to laxatives	Having discussed this treatment at previous meetings, the TAG was generally supportive if the applications but **did not specify** a recommended traffic light classification for the treatment. The applications to be forwarded directly to D&TCG along with the proposed pathway to support local implementation of NICE TA 345.	*The D&TCG debated whether the proposed treatment pathway includes appropriate optimisation of laxative treatment before use of other agents is considered.* *The D&TCG deferred any decision regarding this treatment until the detail of the treatment pathway is clarified.*
Therapeutics Advisory Group: **IFR Panel / Public Health Policy Proposal:**	Cinaclacet (*Mimpara*®)	Primary Hyperparathyroidism	**November 2015:** The TAG recommended that the policy should specify use of cinacalcet only in patients with symptomatic	**November 2015:** *The amended version of the policy was not available at the D&TCG*

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			severe Primary Hyperparathyroidism (PHPT), where normalisation of calcium is desirable, but in whom surgery is not indicated or is contraindicated for clinical reasons. The amended policy to be submitted to the D&TCG for a commissioning decision.	*meeting. The D&TCG agreed with the TAG's recommendations in principle subject to receiving the final version from the author. Once approved, the policy would be further disseminated to the Provider Trusts.* **December 2015:** *Amended policy not available from the author.* **January 2016:** *Policy received and supported for commissioning by the D&TCG as* Red (Hospital/Specialist only).
Therapeutics Advisory Group (TAG): **NNUH Application: (July 2015)** ***Jan- May 2013:*** TAG classified ticagrelor for this indication as Green (GP prescribable following specialist initiation) following the decision to commission as per **NICE TA 236 (Oct 2011)** but with local agreement restricting use in	Ticagrelor (*Brilique*®)	Expansion for use in medically managed patients with ST elevation myocardial infarction, and Non-ST elevation myocardial infarction	**July 2015:** The TAG recognised that no new clinical evidence was presented for this treatment and the decision to be made about the expansion of the treatment group is a commissioning responsibility. No change to the current TAG traffic light classification is necessary – i.e. Green (GP prescribable following specialist initiation).	**July 2015:** *The D&TCG noted the NNUH's application to expand the treatment group at an extra cost of £307,000 p.a. to Primary Care in Central Norfolk.* *The D&TCG recommended that CCG and Trust*

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specified patient groups only. The NNUH now wishes to use ticagrelor as a first-line option for most patients with ACS, beyond the agreement reached in 2013.			Application referred to the CCGs (via the D&TCG) for further discussion and consideration.	*clinicians meet to discuss the relative affordability of this proposal. The previous commissioning decision applies in the interim.* **January 2016:** *Following negotiations between the Trust and the Central Norfolk CCGs and subsequent referral of the cost implications and relative uptake of ticagrelor elsewhere, the D&TCG was advised that the Central Norfolk CCGs' Joint Commissioning Committee had agreed to support use of ticagrelor as per the NNUH's application and revised treatment pathway.*
Therapeutics Advisory Group: **<u>NNUH Application and proposed treatment pathway</u>**	Beclometasone dipropionate 5mg gastro-resistant prolonged-release tablets (*Clipper*®)	Second-line corticosteroid option in the treatment of flares in mild-moderate ulcerative colitis in adults	**November 2015:** The TAG agreed to support the application and recommended a traffic light classification of Green (Specialist initiation / recommendation within the agreed pathway). Regarding the proposed pathway, clarification is needed regarding when	***November 2015:*** *The D&TCG noted that the proposed treatment pathway indicated that Clipper® would be used as an equal option with prednisolone despite it possibly being*

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			Clipper® would be used in preference to prednisolone. Monitoring of use is recommended to ensure that the numbers being treated are within what was expected in the application.	*less effective than other corticosteroid treatment. The committee therefore requested clarification on the circumstances under which Clipper® would be used in preference to prednisolone. To be re-considered by the D&TCG in Dec 2015*. ***December 2015 – January 2016:*** *The D&TCG considered the information provided by the applicant and agreed to commission use of Clipper® as a second line option, after oral prednisolone, and in line with an amended treatment pathway as* Green (Specialist initiation / recommendation within the agreed pathway)*.*