

**North of Tyne and Gateshead
Area Prescribing Committee
Minutes of a meeting held on
Tuesday 12th July 2016
at Northumbria House, Cobalt Business Park, North Tyneside**

Present:

Anne-Marie Bailey (AMB)	Senior Medicines Optimisation Pharmacist	NHS Newcastle Gateshead CCG
Pat Bottrill	Lay Representative	
David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Helen Coundon	GP	NHS North Tyneside CCG
Sue Dickinson (SD)	Director of Pharmacy	RDTTC
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTW
Alexander Dyker	Consultant Clinical Pharmacologist	NUTH
Neil Gammack	Chief Pharmacist	GHFT
Tomal Karim		South Tyneside and Gateshead LPC
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Neil Morris (NM)	Medical Director	NHS Newcastle Gateshead CCG
Helen Seymour (HS)	Senior Medicines Optimisation Pharmacist	NECS
Graham Syers	Prescribing Lead	NHS Northumberland CCG
Simon Thomas (STh)	Consultant Clinical Pharmacologist	NUTH
Susan Turner (STu)	Medicines Optimisation Pharmacist	NECS
Steve Williamson(SW)	Consultant Pharmacist in Cancer Services	NHCT/NHSE

Apologies

Gary Armstrong	Team Leader	Pharmicus
Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
Ian Campbell	Deputy Clinical Director of Pharmacy and Medicines Management	NUTH
Matt Grove	Consultant Rheumatologist and Head of Service	NHCT
Sheetal Sundeep	Consultant Microbiologist	NHCT
Neil Watson(NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Martin Wright	Medical Director	NHS North Tyneside CCG
Andre Yeung	Specialist Pharmacy Advisor - Public Health	Newcastle City Council

GHFT	Gateshead Health NHS Foundation Trust
NoT LPC	North of Tyne Local Pharmaceutical Committee
NHSE	NHS England
NHCT	Northumbria Healthcare NHS Foundation Trust
NECS	North of England Commissioning Support Organisation
NTWT	Northumberland Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTTC	Regional Drugs and Therapeutics Centre

2016/35	<p>Resignations Arpita Bhattacharya has indicated her intention to resign from the committee but has committed to remain until a suitable replacement is found. The committee agreed that DC will speak to the clinical director in Northumbria about a suitable replacement.</p>
2016/36	<p>Declarations of interest No relevant declarations were made.</p>
2016/37	<p>Appeals against previous decisions None.</p>
2016/38	<p>Minutes and decision summary from previous meetings. The following documents were accepted as a true record:</p> <ul style="list-style-type: none"> • Decision summary from 12/4/16. • Minutes from 12/4/16
2016/39	<p>Matters arising not on the agenda or Action Log. None</p>
2016/40	<p>Action Log The action log was reviewed and will be updated to reflect the following progress:</p> <ul style="list-style-type: none"> • 2015/73 –Work on Formulary merging is underway but is taking longer than expected. The merged formulary and new website is expected to be in place by the end of September. • 2016/33 - A document that provided an overview of the available evidence around cost effectiveness of INR Self-Monitoring was considered. It is likely that self-monitoring is a safe option for competent and motivated patients but whilst two UK evaluations conclude that self-monitoring is a cost effective strategy when compared to usual care, further analyses demonstrated that although self- management was cost effective self-testing was not. Commissioners will progress this through the Regional CCG Forum if they decide to take further action although it was agreed that current publicity in relation to perceived benefits to patients and/or the healthcare economy was being generated more by industry than patients. The role of alternative oral anticoagulants, that do not require INR testing, also needs included if any change to service delivery is being considered.
2016/41	<p>Report from the Formulary Sub-committee Formulary version 6.3 is now available on the APC website.</p> <p>Minutes and recommendations from the North of Tyne & Gateshead FSC meeting held on 6th June: The above minutes and recommendations were received by the committee. The summary of decisions made by the committee on new product requests is listed in the decision summary. The following specific points were highlighted for further consideration:</p> <p>Aripiprazole 7.5mg/ml IM injection (Abilify®) for rapid tranquilisation</p> <p>Aripiprazole 7.5mg/ml IM injection had previously been requested for rapid tranquilisation (RT) in patients with acute psychosis and a decision deferred pending receipt of a revised flowchart clearly defining the place in therapy. A revised RT flowchart was presented at the FSC and use in line with that has now been recommended.</p>

Decision: Approved

The request for aripiprazole IM injection was approved in line with the revised flow chart. This is for internal NTW use only.

Qutenza

The Qutenza® Capsaicin 8% patch was first considered by the APC in 2011. It was refused by the APC at appeal, with the caveat that in exceptional cases, such as HIV, IFRs could be used. Subsequently it has been approved by the SMC for peripheral neuropathic pain in non-diabetic adults on the basis of evidence that demonstrated that it is more cost effective compared to pregabalin. It has now been requested for patients who fail to respond to pregabalin. It was agreed that any approval would be on the basis that non-effective treatments should be stopped by the specialist before progressing to Qutenza® use. The committee was minded to support the request subject to the applicant providing clear criteria for the patients who would be eligible for treatment and confirmation that other non-effective treatments would be stopped.

Decision deferred:

The request for Qutenza® Capsaicin 8% patch was deferred until additional information relating to implementation is received.

Thalidomide – Hereditary Haemorrhagic Telangiectasia

Thalidomide has been requested for the treatment of severe epistaxis as a result of hereditary haemorrhagic telangiectasia (HHT) in patients who have failed all other treatments. It has previously been approved for severe bleeding due to bowel dysplasia. The group noted that the evidence that thalidomide was effective in HHT was limited to case studies, but recognised that these patients were at risk of life threatening bleeding. The committee was given assurance that the full safeguards that are in place for its use in myeloma, such as the pregnancy prevention program, would apply to all patients, irrespective of indication. This includes prescribing arrangements and monitoring of other adverse events such as peripheral neuropathy.

Decision: Approved

The request for use of Thalidomide in Hereditary Haemorrhagic Telangiectasia was approved on the understanding that organisations have the appropriate governance arrangements in place.

Glaucoma Preparations

The four applications for glaucoma preparations have currently been withdrawn.

Inhaler Review

The respiratory review group reconvened to review recommendations made around the use of inhalers including LABA/LAMA combinations, branded generics and new products. Due to the merger of the North of Tyne APC and the Gateshead Medicines Management Committee it was also necessary to consider the existing Gateshead formulary recommendations.

It was agreed that switching from originator branded inhalers should only be undertaken with the appropriate level of counselling and inhalers should generally be prescribed by brand name as the device, and ability to use it correctly, was critical to ensuring best outcomes for patients. The APC guideline Branded Prescribing – Medicines that are Not Suitable for Generic Prescribing – Apr 2016 should be followed.

It was recognised that practices are being encouraged to increase their use of newer, more cost effective, branded inhalers. The group felt that this was entirely appropriate, given the current financial pressures, when backed up with effective communication, patient engagement and counselling. Switching of existing patients to newer, more cost effective, devices should only happen, however, following face to face review with the patient.

The following recommendations were endorsed by the committee and, subject to outstanding comments from Gateshead colleagues, will be approved via chairs action:

LAMA

- Glycopyrronium 50 and umeclidinium 55 should be added to the formulary
- Aclidinium is an option for patients who cannot tolerate the other LAMAs
- Tiotropium will remain on formulary for patients unable to use the other LAMA preparations. The (Tiotropium) Respimat® device should be removed from formulary.

LABA/LAMA

- Duaklir Genuair®, Anoro Ellipta®, and Ultibro Breezhaler® will remain on the formulary with Ultibro Breezhaler® placed as the first line option.

LABA

- No changes

ICS/LABA

- Seretide® both Evohaler and Accuhaler will be removed from formulary (for new patients). Appropriate switching is endorsed in line with the principles outlined above.
- Flutiform® (MDI) will remain on formulary.
- Budesonide/formoterol - DuoResp Spiromax® and Symbicort Turbohaler® both approved with DuoResp Spiromax® as first line.
- Relvar Ellipta® 92/22 & 184/22 to remain on formulary as second choice ICS/LABA.
- Beclometasone/formoterol 100/6 & 200/6 (Fostair®) to be retained and Fostair NEXThaler® to be added to formulary, both as a third choice preparations.

ICS

- Budesonide (Turbohaler and Easyhaler) first choice.
- Beclometasone (Clenil and Qvar) alternatives.

An implementation tool that has been developed in Northumberland has been shared with other CCG areas for them to use/adapt as they wish.

2016/42	<p>Report from the Medicines Guidelines and Use Group Minutes from the meeting on 15/6/16 were accepted.</p> <p>Clinical Guidelines for approval:</p> <ul style="list-style-type: none"> • North of Tyne & Gateshead Anti-platelet guidelines - approved • North of Tyne Heart Failure Guideline – approved. These guidelines are being considered by Gateshead colleagues on 13/7/16 to see if they can be endorsed for use in their area. AMB will subsequently contact the Guideline author if there is a desire to rebadge as NoT & Gateshead Guidelines. • Northern East Adult Headache Management Guidelines – endorsed for use. <p>Shared Care Guidelines for approval:</p> <ul style="list-style-type: none"> • Dexamfetamine SCG for the treatment of ADHD in Adults - update approved. • Methylphenidate SCG for the Treatment of ADHD in Adults - update approved. • Lisdexamefetamine SCG for the treatment of ADHD in Children – update approved. • Lithium SCG – update approved. Within this shared care guideline there is acknowledgement that it may be appropriate, with the explicit consent of the GP, the specialist and patient, to discharge some patients from specialist care. Such agreement must be clearly documented in patient notes. The RAG status of Lithium will remain as amber to highlight that discharge to primary care will be by exception and the general rule of shared care still applies to most patients. • Lisdexamfetamine in the Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults. <p>Nefopam Nefopam prescribing rates and costs have risen significantly in recent months. The committee are concerned about inappropriate use both from a cost and safety perspective. Nefopam has a high anticholinergic burden, has a misuse potential, is toxic in overdose and is showing in lab screens as a false positive for benzodiazepines. Members agreed there should be consultation with clinicians around the potential to remove this from the formulary or at least to limit use to clearly defined clinical situations. ML will progress this through the FSC. In the meantime, members are asked to continue to raise awareness of the issues with their clinicians. It was highlighted that there is a limited role recognised within the North of Tyne Non-malignant Pain Guidelines (<u>Analgesic Prescribing Guideline – Non-Malignant Pain – Apr 2015</u>) and, depending on the outcome of the consultation process, these may need revised.</p>
2016/43	<p>Establishing Regional Medicines Optimisation Committees SD gave an update on progress in respect of item 2016/28. 4 task and finish groups have been set up to take the development of the regional committees forward. The committees are now expected to run in shadow form by autumn 2016 and be fully functional in 2017.</p>
2016/44	<p>Psychotropic Medication in People with a Learning Disability The committee noted a briefing guide that has been sent to CCGs by the North East and Cumbria Learning Disabilities Transformation Board's Medicines</p>

	<p>Optimisation group.</p> <p>The briefing is in relation to Psychotropic medication issued to people with learning disabilities for “behaviours that challenge”. National Guidance was issued on 1st June (https://www.england.nhs.uk/wp-content/uploads/2016/06/stopping-over-medication.pdf) and members were asked to ensure clinicians were aware of this.</p> <p>This is a cross sector issue and CPPE are producing educational materials for pharmacists that are due to be launched in the autumn whilst the BMJ has published a press release and review article.</p>
2016/45	<p>NICE Technology Appraisals</p> <p>The following Technology Appraisals were noted and the recommendations within them will be reflected in the formulary:</p> <ul style="list-style-type: none"> • TA 387 Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated • TA 388 Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction • TA 389 Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer • TA390 Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes • TA 391 Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel • TA217 (Updated) Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease • TA392 Adalimumab for treating moderate to severe hidradenitis suppurativa • TA393 Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia • TA394 Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia • TA395 Ceritinib for previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer • TA396 Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma • TA397 Belimumab for treating active autoantibody-positive systemic lupus erythematosus
2016/46	<p>Northern (NHS) Treatment Advisory Group (N-TAG)</p> <p>The following recommendations were finalised by N-TAG at their meeting on the 11/4/16 and are now available on the website</p> <p><u>Latest News NTAG :</u></p> <ul style="list-style-type: none"> • e-Voke® electronic cigarette to relieve and/or prevent withdrawal symptoms and reduce the cravings associated with tobacco dependence – not recommended. • Etanercept Biosimilar (Benepali®) for Rheumatoid arthritis (RA), Axial spondylitis (AS), Psoriatic arthritis and Plaque psoriasis (adults only) - recommended as an option for use in adults where the originator product (Enbrel®) would normally be prescribed. • Transanal Irrigation Systems for neurogenic bowel dysfunction, chronic constipation and chronic faecal incontinence - recommended as an option for treatment when all other treatment options have failed or

	<p>proved ineffective and if initiated and monitored by a specialist.</p> <p>As more biosimilars are introduced to the market the committee was asked if they would have a role in positioning one product over another in future and how/if it could help facilitate more rapid uptake of these agents.</p> <p>Gainshare arrangements, internal trust processes, national professional body position statements and Regional Homecare procurement processes can all influence the speed of uptake and it was noted that the North East have been slower than some other areas to benefit from the introduction of these agents. The APC terms of reference do not currently cover these contractual issues and it was felt that the Regional Medicines Optimisation Committee may be a better forum to progress this.</p>
2016/47	<p>NHS England</p> <p>The following NHS England communications were noted and will be reflected in the formulary:</p> <ul style="list-style-type: none"> • Specialised Commissioning Drugs Briefing – Spring Edition • SSC1620 - Primary Care Responsibilities in Prescribing and Monitoring Hormone Therapy for Transgender and Non-Binary Adults (updated) • SSC1624 - NICE Technology Appraisal 386: Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis • SSC1627 NICE Technology Appraisal 391: Cabazitaxel for hormone relapsed metastatic prostate cancer treated with docetaxel'
2016/48	<p>Chair's action</p> <p>The following three documents have been approved and posted on the APC website:</p> <ul style="list-style-type: none"> • Branded v generic document (update) • Regional antibiotic guidelines (update) • Third Party Ordering Document (update) <p>The previously approved Osteoporosis Guidelines have had approval withdrawn following further feedback on referral thresholds for DEXA scanning. The group is due to reconvene and updated guidelines will be presented to the committee for approval.</p>
2016/49	<p>Any other business</p> <p>SW informed members that there is a new procedure for the Cancer Drugs Fund. He will forward details to the secretary for distribution with the minutes.</p>
2016/50	<p>Date and time of next meeting</p> <p>Tuesday 11th October 2016, 12.30pm Room 4, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside. The meeting will start at 12:30pm</p>
	<p>Signed: Date: 11/10/16 (Chair of the APC)</p>

North of Tyne & Gateshead Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 12th July 2016**.

Classification of products:

R = 'RED' drugs for hospital use only

A = 'AMBER' drugs suitable for use under Shared Care arrangements

B = 'BLUE' drugs initiated in secondary care where an information sheet for GPs is recommended

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
Aripiprazole 7.5mg/ml IM injection (Abilify®) for rapid tranquilisation	✓ R			<p>Aripiprazole 7.5mg/ml IM injection has been requested for rapid tranquilisation (RT) in patients with acute psychosis. Aripiprazole is of similar efficacy to haloperidol and may be better tolerated due to less extrapyramidal symptoms. It is approved by the SMC but it is not recommended in current NICE clinical guidance. NICE recommend IM haloperidol + promethazine or IM lorazepam. Continuing long term supply problems with lorazepam were noted. Use would be solely in NTW.</p> <p>Decision: The request was approved following a revised flow chart outlining where use would be appropriate being provided by NTW.</p>
2) New Requests				
Capsaicin 8% patch (Qutenza®)			✓ R	<p>Application originally rejected by the NoT APC in 2011 at appeal. Approved by the SMC in 2014 for peripheral neuropathic pain in non-diabetic adults on the basis of evidence that demonstrated that it is more cost effective compared to pregabalin. It has now been requested for use in patients who fail to respond to pregabalin. Patient numbers are likely to be self-limiting. The committee questioned the cost effectiveness in combination with other treatments. It was agreed that the non-effective treatment should be stopped and that it should be the specialist that does this.</p> <p>Decision: The committee was minded to support the request subject to the applicant providing clear criteria for the patients who would be eligible for treatment and confirmation that other non-effective treatments would be stopped. Additional information has been requested.</p>

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Ceftobiprole injection (Zevtera®)	✓ R			<p>Ceftobiprole is a new generation cephalosporin, with activity against resistant gram positive organisms such as MRSA and gram negative organisms. This allows it to be used as monotherapy in hospital acquired pneumonia. It has been compared to combination therapy in hospital acquired pneumonia and was found to be non-inferior.</p> <p>Decision: The request for ceftobiprole, for use under microbiology/ID advice, was approved as a red drug.</p>
Brivaracetam (Briviact®) tablets	✓ G plus			<p>Requested for use as adjunctive therapy in partial onset seizures (POS) as per its license. It has been studied in placebo controlled trials but not in head to head studies with other adjunctive therapies including levetiracetam, to which it is structurally related. Results from the placebo controlled studies show that 40% of patients experienced a reduction in seizures by 50%. It is significantly more expensive than levetiracetam but it isn't that much more expensive than some of the other, newer, antiepileptic therapies.</p> <p>Decision: The committee agreed that brivaracetam could be used patients with severe/intractable partial onset seizures e.g. seizure frequency of 1 per week, following the failure of first line adjunctive treatments. The specialist must assess the response within 3-6 months before transferring prescribing to the GP or stopping treatment, as appropriate.</p>
Granisetron 3.1 mg/24 hours patch (Sancuso®)		✓		<p>Previously refused by the APC on the grounds that the Cancer Network did not support its use. It has now been requested for patients with gynaecological cancers who are receiving both chemotherapy and radiotherapy, on the grounds that these patients are at higher risk of diarrhoea. It was noted that the cancer network still did not support its use, suggesting a role for ondansetron oro-dispersible tablets/melts in these circumstances. The group noted the lack of comparative evidence with ondansetron oro-dispersible tablets/melts.</p> <p>Decision: Refused due to lack of comparative evidence with the ondansetron oro-dispersible tablets/melts, that could be used in these types of patients.</p>
3) New formulations & extensions to use				
Humalog 200 units/mL	✓ G plus			<p>Humalog 200 units/mL has been requested as an option for patients requiring higher doses of insulin. This is on the grounds that it is available in a device that only allows units to be selected.</p> <p>Decision: Approved.</p>

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Clindamycin /Tretinoin gel (Treclin®)			✓	<p>Treclin® is a combination topical treatment for moderate acne. Combination therapy is recommended to reduce the development of resistance. The available data shows that Treclin® is superior to monotherapy with clindamycin or Tretinoin. However the absolute benefit compared to clindamycin is modest, although Treclin® is faster acting. It was noted at an acne guideline was being produced by Newcastle Gateshead CCG in conjunction with Dermatology specialists at the RVI.</p> <p>Decision: Deferred subject to rationalisation of topical combination products to be included in the formulary and guideline.</p>
Thalidomide – Hereditary Haemorrhagic Telangiectasia	✓ R			<p>Thalidomide has been requested for the treatment of severe epistaxis as a result of hereditary haemorrhagic telangiectasia (HHT) in patients who have failed all other treatments. It has previously been approved for severe bleeding due to bowel dysplasia. The group noted that the evidence that thalidomide was effective in HHT was limited to case studies, but recognised that these patients were at risk of life threatening bleeding.</p> <p>Decision: Approved. Assurance has been received in relation to the pregnancy prevention program. Organisations must have robust governance processes in place to ensure use is in line with this.</p>
4) NHS England Specialised Services communications noted and endorsed by APC				
Specialised Commissioning Drugs Briefing – Spring Edition	Noted			The formulary will reflect the policy outlined in this circular
SSC1620 - Primary Care Responsibilities in Prescribing and Monitoring Hormone Therapy for Transgender and Non-Binary Adults (updated)	Noted			The formulary will reflect the policy outlined in this circular
SSC1624 - NICE Technology Appraisal 386: Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis	✓ R			The formulary will reflect the policy outlined in this circular

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
SSC1627 NICE Technology Appraisal 391: Cabazitaxel for hormone relapsed metastatic prostate cancer treated with docetaxel	✓ R			The formulary will reflect the policy outlined in this circular
5) Products considered by NICE				
TA 387 Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated	✓ R			The formulary will reflect the position outlined in the TAG
TA 388 Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction	✓ s			The formulary will reflect the position outlined in the TAG
TA 389 Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer	✓ R			The formulary will reflect the position outlined in the TAG
TA390 Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes	✓			The formulary will reflect the position outlined in the TAG
TA 391 Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel	✓ R			The formulary will reflect the position outlined in the TAG
TA217 (Updated) Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease	✓			The formulary will reflect the position outlined in the TAG
TA392 Adalimumab for treating moderate to severe hidradenitis suppurativa	✓ R			The formulary will reflect the position outlined in the TAG

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA393 Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia	✓ R			The formulary will reflect the position outlined in the TAG
TA394 Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia	✓ R			The formulary will reflect the position outlined in the TAG
TA395 Ceritinib for previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer	✓ R			The formulary will reflect the position outlined in the TAG
TA396 Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma	✓ R			The formulary will reflect the position outlined in the TAG
TA397 Belimumab for treating active autoantibody-positive systemic lupus erythematosus	✓ R			The formulary will reflect the position outlined in the TAG
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
e-Voke® electronic cigarette to relieve and/or prevent withdrawal symptoms and reduce the cravings associated with tobacco dependence		✓		
Etanercept Biosimilar (Benepali®) for Rheumatoid arthritis (RA), Axial spondylitis (AS), Psoriatic arthritis and Plaque psoriasis (adults only)	✓ R			Recommended as an option for use in adults where the originator product (Enbrel®) would normally be prescribed.
Transanal Irrigation Systems for neurogenic bowel dysfunction, chronic constipation and chronic faecal incontinence	✓			Recommended as an option for treatment when all other treatment options have failed or proved ineffective and if initiated and monitored by a specialist.
7) Appeals against earlier decisions by the APC				
None				
8) Miscellaneous decisions by the APC				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Magnaphate® (magnesium glycerphosphate) & Yourmag®				There has been a recent price change with Magnaphate® (magnesium glycerphosphate) meaning that it was now more expensive than Yourmag®. The subcommittee agreed to put both preparations on formulary with a statement to use most cost effective brand.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Inhaler Review				<p>Switching of existing patients to newer more cost effective devices should only happen following face to face review with the patient.</p> <p>Inhaler devices should be prescribed by brand in line with the APC guidance on branded prescribing.</p> <p>LAMA</p> <ul style="list-style-type: none"> • Glycopyrronium (Seebri® Breezhaler® 44 micrograms inhalation powder, hard capsules) and umeclidinium (Incruse® 55 micrograms inhalation powder, pre-dispensed) should be added to the formulary (COPD). • Aclidinium is an option for patients who cannot tolerate the other LAMAs (COPD). • Tiotropium will remain on formulary for patients unable to use the other LAMA preparations. Consideration should be given to switching at next review, providing adequate training / counselling is provided in device use. • The (Tiotropium) Respimat® device should be removed from formulary. For asthma the Tiotropium (Handihaler) should be used (off label use). <p>LABA/LAMA</p> <ul style="list-style-type: none"> • Duaklir Genuair®, Anoro Ellipta®, and Ultibro Breezhaler® will remain on with Ultibro Breezhaler® as first line option. <p>LABA</p> <ul style="list-style-type: none"> • No changes <p>ICS/LABA</p> <ul style="list-style-type: none"> • Seretide® both Evohaler and Accuhaler will be removed from formulary (for new patients) with switching as appropriate. • Flutiform® (MDI) to remain on formulary. • Budesonide/formoterol - DuoResp Spiromax® and Symbicort Turbohaler®) to remain on formulary with DuoResp Spiromax® as first line. • Relvar Ellipta® 92/22 & 184/22 to remain on formulary as second choice ICS/LABA. • Beclometasone/formoterol 100/6 & 200/6 (Fostair®) to be retained and Fostair NEXThaler® to be added to formulary, both as a third choice preparations. <p>ICS</p> <ul style="list-style-type: none"> • Budesonide (Turbohaler and Easyhaler) first choice. • Beclometasone (Clenil and Qvar) alternatives.