

**NHS Portsmouth CCG
South Eastern Hampshire CCG
Fareham and Gosport CCG
Portsmouth Hospitals NHS Trust
Southern Health NHS Foundation Trust
Solent NHS Trust**

**Notes from the Area Prescribing Committee Meeting held on Friday February 16th 2018
Room 6, Education Centre, E level, Queen Alexandra Hospital**

Agenda

1.18.1	<p>Present: Alastair Bateman (chair), Michael Bennett-Marsden (acting secretary), Kevin Vernon, Amanda Cooper, Simon Cooper, Ope Owoso, Calvin Rendle, Jason Peett, Debby Crockford, Jon Durand, Mike Stewart, Vanessa Lawrence, Jennifer Etherington, Jonathan Lake, Matthew Puliyl, Simon Norman, Steven Young Min, Christine Minnis.</p> <p>Apologies for absence: Matthew Puliyl (who attended later), Ian Reid</p>	
1.18.1.1	<p>Declarations of Interest: none</p>	
1.18.2	<p>DRAFT Notes of last meeting 15th December 2017 There were a couple of amendments raised to the draft notes:</p> <ul style="list-style-type: none"> • Edoxaban – AC noted that she was still awaiting the amended version of the document, which she requires prior to dissemination for comment. She will distribute when it is received. • APC terms of reference review – The notes mention that the committee would like the attendance of an NMP (nurse) from Portsmouth. This wording is to be changed to ‘from the Portsmouth healthcare economy’. <p>These changes were made to the notes of the last meeting. Otherwise they were agreed as an accurate record.</p>	MBM
1.18.3	<p>Matters arising</p> <ul style="list-style-type: none"> • Final wording of Bone health guidelines & review of formulary decisions - see 1.18.5.5 for further commentary and notes. <p>Additions to the formulary supported by F&M for noting:</p> <p>DispozABLE spacer: For use with bronchodilator MDIs when required for reversibility testing during spirometry. More expensive alternatives are currently used. The DispozABLE spacer is now approved for a trial in E.D. for 4 months (RED). After this time the usage data should be compiled, and the business case resubmitted to F&M.</p> <p>Dupilumab for severe eczema beyond EAMS: For the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy. Dupilumab has previously been available by an EAMS scheme, but this is now closed to new entrants. The company is offering to fund 10 PHT patients prior to a NICE TA being completed. The submitted business case was declined. Mike S suggested that Hywel submit individual IFRs/non-formulary requests for each patient, to be approved prior to the medicine being commenced. This arrangement is to be followed until NICE guidance is published. It was mentioned at the meeting that Mike S has so far not received any</p>	

	IFRs for this drug/indication. Medihoney Barrier Cream: 2 nd line for nappy rash (if improvement is not seen with current first line, Derma S). Medihoney Barrier Cream is approved for addition to the formulary (RED) under advice of tissue viability. Usage is estimated at 2 patients per month.	
1.18.4	Formulary Management – applications for approval	
1.18.4.1	<p>Coding status changes for Lidocaine and Hydrocortisone Phillip Foster was not present to discuss the proposed changes, but they were considered in-absentia.</p> <p>Lidocaine 5% patches – It was proposed that Lidocaine 5% patches have their formulary status changed from RED to GREEN, but with the condition that this product is only prescribed in post-herpetic neuralgia. It was acknowledged that NHS England and NHS clinical commissioners have mentioned this drug in their document <i>'items which should not be prescribed in primary care: guidance for CCGs'</i>, but these recommendations do not apply to patients treated in line with NICE CG173 but are still experiencing neuropathic pain associated with herpes zoster infection (post-herpetic neuralgia).</p> <p>Hydrocortisone Sodium Phosphate Injection – It was proposed that hydrocortisone sodium phosphate injection be changed from RED to AMBER. It was stated that generally patients were initiated this drug by Endocrinology for adrenal crisis, but when it went out of date the patients may be better served by obtaining a replacement via a GP FP10 rather than via secondary care. This proposal has been supported by Partha Kar and Prof Mike Cummings.</p> <p>APC Decision: Both changes were approved by the APC committee. The Portsmouth and South East Hampshire Formulary will be amended in line with the proposals.</p>	MBM
1.18.5	Drug therapy and shared care guidance for approval	
1.18.5.1	<p>Shared care agreements for Acamprosate Christine Minnis attended to present this shared care agreement, which is an update to the 2015 guideline (now out of date and due for review).</p> <p>The APC committee identified several changes that needed to be made to the document:</p> <ul style="list-style-type: none"> • AB requested that the document wording be changed so that the GP is 'requested' to initiate shared care. Currently the document is authoritative in tone, and belies the fact that this is an agreement, not a mandate. It was further acknowledged that some GPs may refuse this shared care agreement, and there needs to be a stated mechanism to deal with this eventuality (and that this is a theme in general, not just with this document). • SC identified that the GP was being requested to take prescribing responsibility at 4 weeks from drug initiation, although the initiating secondary care consultant will be reviewing the patient at 3 weekly intervals for the first 12 weeks. It was requested that the document be changed so that the GP picks up the patient after 12 weeks. • JE mentioned that the document stipulated doses based on patient weight, but that there was no indication whose responsibility it would be to weigh the patient. 	CM

	APC Decision: Provisionally accepted. Document to be revised and then sent to the chair for chairman's approval.	
1.18.5.2	<p>Glaucoma Prescribing Guidelines This document was submitted by Chris Stevens, who was not present to discuss the document. The APC committee did not have any recommendations or comments on the document.</p> <p>APC Action: For noting.</p>	
1.18.5.3	<p>Commissioning arrangements for Liver transplant medications This item was combined with 1.18.6.10 and is discussed later in this document.</p>	
1.18.5.4	<p>Inflammatory arthritis biologic pathways Simon Norman and Dr Stephen Young-Min attended to present these documents. Olumiant (baricitinib) is a JAK inhibitor and is used to treat moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug(s). It comes as an oral preparation and is delivered via a third-party homecare provider. Last year on the 9th of August NICE issued guidance regarding the use of baricitinib for severe rheumatoid arthritis (TA466). This TA was approved for local use by the APC in late 2017. The guidance states that if a patient has a DAS28 score of more than 5.1 and has tried and failed a combination of conventional DMARDs, then they are eligible to start treatment with baricitinib. If, however, they have already tried and failed an anti-TNF medicine, then they must first receive rituximab prior to starting treatment with baricitinib, or to directly quote the guidance text; 'cannot use rituximab'. The issue is that there are valid reasons not to use rituximab that could be considered preferences rather than contraindications (and skipping straight to baricitinib would therefore be treating outside NICE guidance). SYM & SN submitted these documents to elicit debate and try to clarify the use of the term "cannot use rituximab".</p> <p>There was debate about this issue. AC mentioned that current advice was to use the best value biologic, and SYM noted that baricitinib is cheaper than rituximab when a lower dose is needed (but not the higher dose). Baricitinib is also an oral preparation, so may be more appropriate in certain circumstances. AB noted that the documents were a little confusing as they mixed up generic drug names and brands, which made following them difficult. Nevertheless, it was agreed that it was not the committee's role or purview to interpret NICE guidance and that this should be clarified by NICE themselves.</p> <p>APC action: For noting. AB stated that it is not the role of the committee to clarify NICE guidance. This should instead be discussed and agreed locally with specialist doctors and pharmacists until NICE publish advice and clarify their position.</p>	SYM
1.18.5.5	<p>Final wording of Bone health guidelines Simon Norman and Dr Stephen Young-Min attended to present these updated guidelines, which were last presented at the APC in December 2017. There were a few notable changes:</p> <ul style="list-style-type: none"> • Formatting issues (especially inappropriate underlining) have 	

	<p>been corrected.</p> <ul style="list-style-type: none"> • NICE TA464 recommends the use of the FRAX 10-year risk score, but this is an insensitive clinical scoring system which can lead to false positives in a percentage of the population. NICE have since clarified that FRAX is an indicator but not a clinical intervention threshold. SYM has added a box to page 2 of the document, and comments throughout, to aid interpretation of the FRAX score. • Ibandronate has been added to the guidance as it is NICE approved. • Page 8 has been amended to clarify bisphosphonates in order of clinical preference. <p>AB had concerns over the length and complexity of the document but agreed with SYM that bone health is a complex issue, and the guideline tries to give careful, comprehensive and nuanced advice. It was decided that it is easier to follow than first impressions.</p> <p>Following discussion of the guidance, the APC committee considered the proposal to add Binosto to the Portsmouth and South East Hampshire Formulary. There were several concerns that Binosto was just as difficult to take as Alendronate, and the only benefit it offered was that it was easier to swallow in patients with difficulties. Alendronate tablets disperse in 10 mL of water within 2–5 minutes to give very fine particles that disperse easily. All other warnings for Binosto were still the same as Alendronate tablets, and the patient would still need to sit in an upright position when taking the medication. As such, it would offer poor value to the local healthcare economy.</p> <p>APC decision - Provisionally accepted. Guidelines to be revised to remove Binosto and then sent to the chair for chairman's approval. Ibandronate will be added to the formulary as per NICE guidance.</p>	<p>SYM/MBM /SB</p>
<p>1.18.6</p>	<p>Items for note/consultation</p>	
<p>1.18.6.1</p>	<p>NICE Guidance Guidance published in December 2017:</p> <p>CG 128 Autism spectrum disorder in under 19s: recognition, referral and diagnosis</p> <p>This guideline covers recognising and diagnosing autism spectrum disorder in children and young people from birth up to 19 years. It also covers referral. It aims to improve the experience of children, young people and those who care for them. In December 2017, we reviewed the evidence and added ADHD as a factor associated with an increased prevalence of autism and changed references from DSM-4 to DSM-5. This guideline includes recommendations on:</p> <ul style="list-style-type: none"> • local pathway for recognition, referral and diagnostic assessment of possible autism • recognising children and young people with possible autism • referring children and young people to the autism team • autism diagnostic assessment for children and young people • medical investigations • communicating the results from the autism diagnostic assessment • information and support for families and carers <p>Action: For information</p>	

TA 495 Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer

Palbociclib, with an aromatase inhibitor, is recommended within its marketing authorisation, as an option for treating hormone receptor-positive, human epidermal growth factor receptor 2-negative, locally advanced or metastatic breast cancer as initial endocrine-based therapy in adults. Palbociclib is recommended only if the company provides it with the discount agreed in the patient access scheme.

Action: Palbociclib will be added to the formulary with a link to TA 495.

TA 496 Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer

Ribociclib, with an aromatase inhibitor, is recommended within its marketing authorisation, as an option for treating hormone receptor-positive, human epidermal growth factor receptor 2-negative, locally advanced or metastatic breast cancer as initial endocrine-based therapy in adults. Ribociclib is recommended only if the company provides it with the discount agreed in the patient access scheme.

Action: Ribociclib will be added to the formulary with a link to TA 496.

DG 14 Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point of care coagulometers (the CoaguChek XS system)

The CoaguChek XS system is recommended for self-monitoring coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if: the person prefers this form of testing and the person or their carer is both physically and cognitively able to self-monitor effectively.

For information only.

TA 494 Naltrexone–bupropion (Mysimba) for managing overweight and obesity

Naltrexone–bupropion is not recommended within its marketing authorisation for managing overweight and obesity in adults alongside a reduced-calorie diet and increased physical activity. This recommendation is not intended to affect treatment with naltrexone–bupropion that was started in the NHS before this guidance was published. Adults having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

Not recommended & not on formulary. No action required.

TA 492 Atezolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable

Atezolizumab is recommended for use within the Cancer Drugs Fund as an option for untreated locally advanced or metastatic urothelial carcinoma in adults, for whom cisplatin-based chemotherapy is unsuitable, only if the conditions of the managed access agreement for atezolizumab are followed.

Key patient eligibility criteria for atezolizumab use in the Cancer Drugs Fund include:

- Patient has histologically or cytologically documented transitional cell carcinoma of the urothelial tract

- Patient has disease that is either locally advanced (i.e. T4b any N or any T N2-3 disease) or metastatic (any T any N M1 disease)
 - Patient has not received previous chemotherapy for inoperable locally advanced or metastatic urothelial cancer
 - Patient has EITHER not received previous adjuvant chemotherapy, neoadjuvant chemotherapy or chemo-radiotherapy OR, if previously treated with platinum-based chemotherapy whether as adjuvant chemotherapy or as neoadjuvant chemotherapy or with chemo-radiotherapy, has relapsed more than 12 months since completing the platinum-based chemotherapy*
 - Patients meeting this criterion are eligible to be considered as treatment naïve for locally advanced/ metastatic disease but must satisfy all other criteria
 - Patient has an ECOG performance status of 0 -2
 - Patient is ineligible for cisplatin based chemotherapy due to one or more of the following:
 - impaired renal function (EDTA-assessed glomerular filtration rate >30 and <60mls/min)
 - hearing loss of 25dB as assessed by formal audiometry
 - NCI CTCAE grade 2 or worse peripheral neuropathy
 - ECOG performance status of 2
 - Patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody
 - Patient to be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner
 - Treatment breaks of up to 12 weeks beyond the expected cycle
- Action:** Atezolizumab will be added to the formulary with a link to TA 492.

TA 493 Cladribine tablets for treating relapsing–remitting multiple sclerosis

Cladribine tablets are recommended as an option for treating highly active multiple sclerosis in adults, only if the person has:

- rapidly evolving severe relapsing–remitting multiple sclerosis, that is, at least 2 relapses in the previous year and at least 1 T1 gadolinium-enhancing lesion at baseline MRI or
- relapsing–remitting multiple sclerosis that has responded inadequately to treatment with disease-modifying therapy, defined as 1 relapse in the previous year and MRI evidence of disease activity.

Action: Cladribine tablets will be added to the formulary with a link to TA 493.

Guidance published in January 2018:

TA 502 Ibrutinib for treating relapsed or refractory mantle cell lymphoma

Ibrutinib is recommended as an option for treating relapsed or refractory mantle cell lymphoma in adults, only if:

- they have had only 1 previous line of therapy and
- the company provides ibrutinib with the discount agreed in the commercial access agreement with NHS England.

Action: The formulary entry for Ibrutinib will be amended with a link to TA 502

TA 503 Fulvestrant for untreated locally advanced or metastatic

oestrogen-receptor positive breast cancer

Fulvestrant is not recommended, within its marketing authorisation, for treating locally advanced or metastatic oestrogen-receptor positive breast cancer in postmenopausal women who have not had endocrine therapy before.

Action: Not recommended (not cost-effective). No action required.

NG 84 Sore throat (acute): antimicrobial prescribing

This guideline includes recommendations on:

- 1.1 Managing acute sore throat
- 1.2 Self-care
- 1.3 Choice of antibiotic

For information**NG 83 Oesophago-gastric cancer: assessment and management in adults**

This guideline covers assessing and managing oesophago-gastric cancer in adults, including radical and palliative treatment and nutritional support. It aims to reduce variation in practice through better organisation of care and support, and improve quality of life and survival by giving advice on the most suitable treatments depending on cancer type, stage and location.

This guideline includes recommendations on:

- radical and palliative treatment
- nutritional support
- follow-up and support
- service organisation

For information**TA 498 Lenvatinib with everolimus for previously treated advanced renal cell carcinoma**

Lenvatinib plus everolimus is recommended as an option for treating advanced renal cell carcinoma in adults who have had 1 previous vascular endothelial growth factor (VEGF)-targeted therapy, only if:

- their Eastern Cooperative Oncology Group (ECOG) performance status score is 0 or 1 and
- the company provides lenvatinib with the discount agreed in the patient access scheme.

Action: The formulary entry for Lenvatinib will be amended with a link to TA 498

TA 499 Glecaprevir–pibrentasvir for treating chronic hepatitis C

Glecaprevir–pibrentasvir is recommended, within its marketing authorisation, as an option for treating chronic hepatitis C in adults, only if the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit.

Action: The formulary entry for Glecaprevir–pibrentasvir will be amended with a link to TA 499

TA 500 Ceritinib for untreated ALK-positive non-small-cell lung cancer

Ceritinib is recommended, within its marketing authorisation, as an option for untreated anaplastic lymphoma kinase (ALK) positive advanced non-small-cell lung cancer in adults, only if the company provides it with the discount agreed in the patient access scheme.

Action: The formulary entry for ceritinib will be amended with a link to TA 500

	<p>NG 82 Age-related macular degeneration This guideline covers diagnosing and managing age-related macular degeneration (AMD) in adults. It aims to improve the speed at which people are diagnosed and treated to prevent loss of sight.</p> <p>This guideline includes recommendations on:</p> <ul style="list-style-type: none"> • classifying AMD • providing information and support • risk factors • diagnosis and referral • pharmacological and non-pharmacological management • monitoring <p>For information</p> <p>TA 497 Golimumab for treating non-radiographic axial spondyloarthritis Golimumab is recommended, within its marketing authorisation, as an option for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, nonsteroidal anti-inflammatory drugs. If patients and their clinicians consider golimumab to be one of a range of suitable treatments, including adalimumab, etanercept and certolizumab pegol, the least expensive (taking into account administration costs and patient access schemes) should be chosen.</p> <p>Assess the response to golimumab 12 weeks after the start of treatment. Continue treatment only if there is clear evidence of response, defined as:</p> <ul style="list-style-type: none"> • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and • a reduction in the spinal pain visual analogue scale (VAS) score by 2 cm or more. <p>Action: The formulary entry for golimumab will be amended with a link to TA 497</p>	
1.18.6.2	EAMS: No EAMS submissions were received for this meeting.	
1.18.6.3	<p>DPC Agenda (February 2018) The agenda was received for the DPC meeting on Tuesday 13 February 2018, 1- 4pm. Minutes were not available prior to the APC meeting.</p>	
1.18.6.4	<p>Hampshire Medicines Safety Group The notes from the previous meeting on Monday 19th January were reviewed.</p> <ul style="list-style-type: none"> • It was noted that co-dydramol is now available with a higher strength of dihydrocodeine (co-dydramol 20/500 mg and 30/500 mg tablets). It is therefore important that co-dydramol products are prescribed and dispensed by strength to minimise dispensing errors and the risk of accidental opioid overdose. • Following a serious incident, it was stated that morphine liquid should not have directions of 'take as directed' but needs to have a specific dose and maximum of daily doses within a 24 hour period. A discussion ensued, and it was decided that other drugs fitted into this area that also need to be considered (i.e. lorazepam, haloperidol, diazepam and clonazepam). The group was tasked to go away and think about how this might be done, and a decision will be made at next meeting. 	

	There were no new issues for APC to consider. An action tracker (requested by SC at the December 2017 APC) was provided.	
1.18.6.5	<p>Drug Safety Update and Patient Safety Alerts</p> <ul style="list-style-type: none"> • Gadolinium-containing contrast agents: removal of Omniscan and iv Magnevist, restrictions to the use of other linear agents • Cladribine (Litak, Leustat) for leukaemia: reports of progressive multifocal encephalopathy (PML); stop treatment if PML is suspected • Radium-223 dichloride (Xofigo ▼): do not use in combination with abiraterone and prednisone/prednisolone following clinical trial signal of increased risk of death and fractures • Eluxadoline (Truberzi ▼): risk of pancreatitis; do not use in patients who have undergone cholecystectomy or in those with biliary disorders • Fingolimod (Gilenya ▼): new contraindications in relation to cardiac risk • Fingolimod (Gilenya ▼): updated advice about risk of cancers and serious infections • Daclizumab (Zinbryta ▼) and risk of severe liver injury: new restrictions to use and strengthened liver monitoring • Recombinant human erythropoietins: very rare risk of severe cutaneous adverse reactions (SCARs) • Drug-name confusion: reminder to be vigilant for potential errors • Co-dydramol: prescribe and dispense by strength to minimise risk of medication error • Herbal medicines: report suspected adverse reactions via the Yellow Card Scheme 	
1.18.6.6	<p>Regional Medicines Optimisation Committees</p> <p>The agenda was received for the RMOC (South) on 30th January 2018, 10:00-14:00. Minutes were not available prior to the APC meeting.</p>	
1.18.6.7	<p>NHSE Specialised Commissioning</p> <p>No items were submitted for this meeting.</p>	
1.18.6.8	<p>FreeStyle Libre – Implementation process pending adoption of the SHIP 8 priorities statement on its use</p> <p>The Freestyle Libre iCGM Clinical Use Process Pathway (draft proposal) was submitted by Iain Cranston to APC for comment.</p> <ul style="list-style-type: none"> • SC & SB noted that the document did not match the SHIP8 eligibility criteria. It would need to be amended to match or could be open to challenge. • AB & JP mentioned that there could be a potential issue relating to supply of Libre started by the diabetes centre, but which did not meet the new usage criteria in the document when finalized. With this in mind, consideration needs to be made on how to handle this affected cohort in the document. • SC had concerns about introduction of the device and requested a process/criteria for implementation to prevent a sudden deluge of prescriptions for the device/strips. SC also questioned the large supply quantity, and believed that a shorter review duration of 3 months would elicit better patient management. Furthermore, there were still issues relating to the DVLA and testing strips that need to be clarified. He was, however, happy to avoid the need for 	SC/IC/AB

	<p>two separate blood glucose devices. And finally, the document needed to give more detail regarding handover of patients from secondary to primary care.</p> <ul style="list-style-type: none"> • AB stated that he would like to see a comment regarding patients who have become stabilized on the system. When the patient attains long-term control of their condition, when should usage of the device be reviewed? <p>Action: SC will go back to the author and ask him to make it fit the SHIP8 criteria exactly. Once revised, the document is to be returned to the chair for chairman's approval. The scheme is to be audited 9-12 months after starting to review implementation.</p>	
1.18.6.9	<p>Withdrawal of Glucodrate</p> <p>Glucodrate is a food for special medical purposes for use in the dietary management of short bowel-associated intestinal failure and intestinal insufficiency in adults. Glucodrate as approved by ACBS in March 2016 and launched in the UK in January 2017. The manufacturer has received several reports where patients taking gluconate and subsequently developed a disordered blood biochemistry. The manufacturer is not confident that all patients taking Glucodrate in the community are being adequately monitored and have expert hospital supervision available, as recommended by ACBS for prescription of borderline substances. As patient safety cannot be guaranteed, the manufacturer has proactively decided to withdraw Glucodrate from the market, effective Monday 5th February 2018.</p> <p>APC Action: For noting. Glucodrate will be removed from the formulary.</p>	MBM
1.18.6.10	<p>DATIX 41434 Discussion - supply of medications for a liver transplant patient under the Royal Free</p> <p>Christine Minnis presented an incident & complaint reported via QUASAR. A patient formerly managed by the Royal Free for hepatic transplant had been subsequently discharged, but there were numerous issues relating to supply of their medication by primary care (as no shared care arrangement is in place) and communication to the patient (and Royal Free) via PHT secondary care.</p> <p>AC commented that 10 years ago, transplantation services and secondary care were funded to manage the patient for 100 days, then the rest would be handled by primary care. This scheme has since lapsed. HCE are currently reviewing tertiary care arrangements, but only renal transplant has been handled so far. A hub & spoke contracting system for hepatic transplant would be optimal, but so far this has not been considered. It was unknown why Royal Free were not managing this patient via homecare. There is currently no shared care agreement in place with GPs for management of hepatic transplant immunosuppressants, which means that GPs are unprepared and not funded for managing these patients.</p> <p>CM replied that communication issues have been raised at MDT meetings, but the underlying issues need to be fed back to NHS commissioners.</p> <p>Action: AC will contact NHS England and formerly request that a hub & spoke arrangement for managing these patients is considered. CM will feed back the issues and related conversation to Lake Road surgery</p>	AC/CM

	and Hepatology. Short-term medication supplies will be continued by secondary care, where appropriate, until these issues are resolved.	
1.18.6.11	<p>MHRA drug alert - Esmya (ulipristal acetate) for uterine fibroids</p> <p>Esmya was first authorised in 2012 for intermittent or pre-operative treatment of moderate to severe symptoms of uterine fibroids in women of reproductive age. Each treatment course of 5mg daily lasts for up to 3 months and may be repeated with breaks between each course. Five reports of serious liver injury, including four cases of hepatic failure needing liver transplantation, have been reported worldwide in women using Esmya for uterine fibroids. The following temporary safety measures have been introduced while an EU-wide review of the evidence is ongoing:</p> <ul style="list-style-type: none"> • Do not initiate new treatment courses of Esmya, including in women who have completed one or more treatment courses previously • Perform liver function tests at least once a month in all women currently taking Esmya. Stop Esmya treatment in any woman who develops transaminase levels more than 2 times the upper limit of normal, closely monitor and refer for specialist hepatology evaluation as clinically indicated. Liver function tests should be repeated in all women 2 to 4 weeks after stopping treatment. • Check transaminase levels immediately in current or recent users of Esmya who present with signs or symptoms suggestive of liver injury (such as nausea, vomiting, malaise, right hypochondrial pain, anorexia, asthenia, jaundice). If transaminase levels are more than 2 times the upper limit of normal, stop treatment, closely monitor and refer for specialist hepatology evaluation as clinically indicated. • Advise women using Esmya on the signs and symptoms of liver injury. <p>Action: A business case for Esmya (ulipristal acetate) has previously been submitted to APC for consideration, but was deferred as the applicants were unable to attend. This business case will now be deferred indefinitely until the manufacturer change their recommendations, and the business case is resubmitted.</p>	
1.18.7	<p>Any other business:</p> <p>JE reported that Solent and Southern CCGs are currently liaising over an incontinence formulary. This will be brought to APC for noting when appropriate.</p>	
1.18.8	<p>Dates of future meetings:</p> <p>Dates for 2018: Friday April 20th 2018 Friday June 16th 2018 Friday August 17th 2018 Friday October 19th 2018 Friday December 14th 2018</p>	