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

Area Prescribing Committee Meeting, 12.45 for 1.00pm on Friday 17th August 2018
Room 6, Education Centre, E level, Queen Alexandra Hospital

Notes

4.18.1	**Present:** Alastair Bateman (Chair), Jo Williams (Secretary), Amanda Cooper, Vanessa Lawrence, Jennifer Etherington, Jason Peett, Simon Cooper, Mike Stewart, Jon Durand, Phil Foster, Samantha Reilly (observer), Quadri Olaniyan (observer) **Apologies for absence** Jonathan Lake, Kevin Vernon, Raj Parekh, Ian Reid, Deborah Crockford	
4.18.1.1	**Declarations of Interest** None	
4.18.2	**DRAFT Notes of last meeting June 2018** Accepted as accurate. Actions: 3.18.4.1: Kyleena and Jaydess. JE is still waiting for public health England (commissioners of these devices) to approve their use. SC has said he will help to chase this. 3.18.4.3 Sacubitril valsartan. Still awaiting paperwork from Geraint Morton. JW to chase 3.18.5.1 SCAN antibiotic guidelines – returning for discussion (see below)	JE/SC JW
4.18.3	**Matters arising** **Chair's actions since previous meeting:** 1. Shared Care Agreement for Dimethyl fumarate (Skilarence) for the treatment of psoriasis. **APC decision:** accepted by committee **Additions to the formulary supported by F&M for noting:** 1. Rituximab for glomerulonephritis. Approved for a 12 month trial. Not commissioned for this indication. To be added as a RED drug pending receipt of requested paperwork.	
4.18.4	**Formulary Management – applications for approval**	
4.18.4.1	**Glycopyrronium bromide for drooling in Parkinson's disease** This was presented by JE Request for glycopyrronium to be added to the formulary for use in Parkinson's disease patients at risk of aspiration due to drooling. The request is from a specialist nurse within Solent and therefore the case was presented based on Portsmouth area numbers only. NICE guidance supports the use of glycopyrronium for this indication in place of conventionally used treatments. There are now licensed preparations available (licensed for other indication). According to the business case, the cost for treating 8 patients with the licensed liquid preparation will be	

	approximately £300k per annum. This is a significant cost pressure to the local economy. **APC decision:** Request for SHFT to review and submit a joint application and discuss with local consultants to ensure support. JW to contact local consultants with interest in PD. No decision made. For resubmission.	 JE/VL JW
4.18.4.2	**Pregabalin for Anxiety** Presented by AB. A concern has been raised in the community that the formulary status of pregabalin has not been reviewed following the publication of SHFT guidelines, these support the use of pregabalin for anxiety. **APC decision:** The formulary entry for pregabalin for anxiety will be amended and changed to GREEN.	
4.18.5	**Drug therapy and shared care guidance for approval**	
	Infant feeding guidance Presented by JP This is the latest version of the infant feeding guideline produced for the Wessex region. This is an update of the previously approved guideline. **APC decision:** The Wessex infant feeding guideline is approved for use. Previous versions should be removed and replaced with the updated guidance.	
4.18.6	**Items for note/consultation**	
4.18.6.1	**Coagucheck PHT patient contract** Presented by JW A request had been received for the coagucheck patient contract to be added to NetFormulary. This is a contract between the anticoagulant clinic and the patient. The device can not be prescribed on the NHS but the test strips can be. There is a small cohort of patients using the device in the area. **APC decision:** This is a PHT document. Not suitable for NetFormulary. The introduction of NOACs is likely to reduce the number of patients using warfarin.	
4.18.6.2	**SCAN antibiotic guidelines version 2** Adel Sheikh presented the Antibiotic guideline on behalf of the SCAN group (Vice Chair). Dr Sebastien Austin and Nicola Hill were invited to represent the paediatric team's opinion. This is an updated version of the 2018 guideline. The guidance has been approved by other area prescribing committees including the DPC. There was suggestion that resource is needed from primary care to support the governance of the document. There was discussion about the merits of the document and also whether other national guidance could be used in place of the guideline e.g. NICE/PHE. There was lengthy discussion about the concerns raised from the previous	

	version of the document and that many of these concerns have not been resolved in the latest version of the document.
	
	The APC concerns include:
	• The governance process;
	  ○ The guidance was published prior to approval at area prescribing committees.
	  ○ Members of the APC who have been involved in SCAN work suggested that some of the monographs for the document were written two years ago.
	  ○ Members of the SCAN group were not informed that an updated guideline had been published.
	  ○ There is no version control or review date.
	  ○ There are discussions that the document will be available as an ebook. It is unclear how users would be reliably informed if updates have occurred after the document has been downloaded. Suggestion that a website would be more suitable.
	• Paediatric section;
	  ○ Doses are at odds to those recommended in the paediatric BNF. This is the reference source supported by PHT for all trainees and NMPs to use.
	  ○ Evidence from reference sources are poor quality.
	  ○ The references should accurately reflect the source document. The BNF is regularly quoted as the reference for doses when they do not correspond.
	  ○ References for BD dosing for amoxicillin support once daily dosing for adherence (this is not specific to amoxicillin or antibiotics in general), the references do not support efficacy of amoxicillin at BD doses.
	  ○ Recommendation for cephalosporin use does not follow the principles for antimicrobial stewardship.
	  ○ Need to consider the consistency of the choices made e.g. azithromycin for some and clarithromycin for others
	
	APC decision
	The committee have requested that the concerns raised are fed back to the SCAN group. The committee does not support the paediatric section of the guidance and concerns exist around the governance of the guidance as a whole.
	SC to take to Wessex leads CCG forum to discuss.
		JW/AS
		
		SC

4.18.6.3	**Amber drugs** Discussion from members of the APC requesting clarification of what the Amber status of drug means. Can a primary care clinician prescribe the first prescription at the request of a specialist? **APC decision** In order to clarify prescribing status Amber will be split in to three categories: • Amber Initiated: first prescription from specialist, ongoing supplies from primary care (or when stabilised on therapy). • Amber Recommended: first prescription can be supplied by primary care under the advice of a specialist. • Amber Shared Care: first prescription supplied by the specialist. Primary care to continue supplies as agreed within the shared care guideline.	

4.18.6.4	**NICE Guidance** **Guidance Published in June** **TA 521 Guselkumab for treating moderate to severe plaque psoriasis** Guselkumab is recommended as an option for treating plaque psoriasis in adults, only if: • the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and • the disease has not responded to other systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet A radiation), or these options are contraindicated or not tolerated and • the company provides the drug according to the commercial arrangement. **Resource impact:** This technology is commissioned by CCGs. Because guselkumab has been recommended through the fast track approval process the guidance must be implemented within 30 days. **Action:** Guselkumab will be added to the area prescribing formulary with a link to NICE TA 521 **TA 522 Pembrolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable** Pembrolizumab is recommended for use within the Cancer Drugs Fund as an option for untreated locally advanced or metastatic urothelial carcinoma in adults when cisplatin-containing chemotherapy is unsuitable, only if: • pembrolizumab is stopped at 2 years of uninterrupted treatment or earlier if the disease progresses and • the conditions of the managed access agreement for pembrolizumab are followed. **Resource impact:** This technology will be available via the Cancer Drugs Fund **Action:** Pembrolizumab formulary entry will be amended with a link to NICE TA 522 **TA 523 Midostaurin for untreated acute myeloid leukaemia** Midostaurin is recommended, within its marketing authorisation, as an option in adults for treating newly diagnosed acute FLT3-mutation-positive myeloid leukaemia with standard daunorubicin and cytarabine as induction therapy, with high-dose cytarabine as consolidation therapy, and alone after complete response as maintenance therapy. It is recommended only if the company provides midostaurin with the discount agreed in the patient access scheme. **Resource impact:** This technology will be commissioned by NHS England. **Action:** Midostaurin will be added to the area prescribing formulary as RED with a link to NICE TA 523 **TA 524 Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma** Brentuximab vedotin is recommended as an option for treating	

	CD30-positive Hodgkin lymphoma in adults with relapsed or refractory disease, only if: • they have already had autologous stem cell transplant or • they have already had at least 2 previous therapies when autologous stem cell transplant or multi-agent chemotherapy are not suitable and • the company provides brentuximab vedotin according to the commercial arrangement. **Resource impact:** The technology is commissioned by NHS England. **Action:** Brentuximab vedotin formulary entry will be amended with a link to NICE TA 524. **TA 525 Atezolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy** Atezolizumab is recommended as an option for treating locally advanced or metastatic urothelial carcinoma in adults who have had platinum-containing chemotherapy, only if: • atezolizumab is stopped at 2 years of uninterrupted treatment or earlier if the disease progresses and • the company provides atezolizumab with the discount agreed in the patient access scheme. **Resource impact:** The technology is commissioned by NHS England. **Action:** Atezolizumab formulary entry will be amended with a link to NICE TA 525 **TA 526 Arsenic trioxide for treating acute promyelocytic leukaemia** Arsenic trioxide is recommended, within its marketing authorisation, as an option for inducing remission and consolidation in acute promyelocytic leukaemia (characterised by the presence of the t[15;17] translocation or the PML/RAR-alpha gene) in adults with: • untreated, low-to-intermediate risk disease (defined as a white blood cell count of $10x10^3$ per microlitre or less), when given with all-trans-retinoic acid (ATRA) • relapsed or refractory disease, after a retinoid and chemotherapy. **Resource impact:** This technology is commissioned by NHS England **Action:** Arsenic trioxide formulary entry will be amended with a link to NICE TA 526 **TA 527 Beta interferons and glatiramer acetate for treating multiple sclerosis** 1. Interferon beta-1a is recommended as an option for treating multiple sclerosis, only if: • the person has relapsing–remitting multiple sclerosis and • the companies provide it according to commercial arrangements. 2. Interferon beta-1b (Extavia) is recommended as an option for treating multiple sclerosis, only if: • the person has relapsing–remitting multiple sclerosis and has had 2 or more relapses within the last 2 years or • the person has secondary progressive multiple sclerosis with continuing relapses and • the company provides it according to the commercial arrangement.	

	3. Glatiramer acetate is recommended as an option for treating multiple sclerosis, only if: • the person has relapsing–remitting multiple sclerosis and • the company provides it according to the commercial arrangement. 4. Interferon beta-1b (Betaferon) is not recommended within its marketing authorisation as an option for treating multiple sclerosis. **Resource impact:** These technologies are commissioned by NHS England. **Action:** Extavia, Avonex, Rebif and Glatiramer acetate will be added to the area prescribing formulary as RED with a link to NICE TA 527. **NG 97 Dementia: assessment, management and support for people living with dementia and their carers** This guideline covers diagnosing and managing dementia (including Alzheimer's disease). It aims to improve care by making recommendations on training staff and helping carers to support people living with dementia. **Action required:** Guidance changes place of therapy for memantine which suggests that the treatment may be initiated by primary care. The shared care agreement is under review by Southern Health. **NG 98 Hearing loss in adults: assessment and management** This guideline covers some aspects of assessing and managing hearing loss in primary, community and secondary care. It aims to improve the quality of life for adults with hearing loss by advising healthcare staff on assessing hearing difficulties, managing earwax and referring people for audiological or specialist assessment and management. **For information** Practices may need to review their procedures for ear wax removal. **Guidance Published July 2018** **TA 528 Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer** Niraparib is recommended for use within the Cancer Drugs Fund as an option for treating relapsed, platinum-sensitive high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to the most recent course of platinum-based chemotherapy in adults, only if: • they have a germline BRCA mutation and have had 2 courses of platinum-based chemotherapy or • they do not have a germline BRCA mutation and have had 2 or more courses of platinum-based chemotherapy and • the conditions in the managed access agreement for niraparib are followed. **Resource impact:** This technology will be made available through the cancer drugs fund. **Action:** Niraparib will be added to the area prescribing formulary as RED with a link to NICE TA 528 **TA 529 Crizotinib for treating ROS1-positive advanced non-small-cell lung cancer** Crizotinib is recommended for use within the Cancer Drugs Fund as an option for treating ROS1-positive advanced non-small-cell lung cancer	VL

	(NSCLC) in adults, only if the conditions in the managed access agreement are followed. **Resource impact:** This technology will be made available through the cancer drugs fund. **Action:** The formulary entry for Crizotinib will be updated with a link to NICE TA 529. **TA 530 Nivolumab for treating locally advanced unresectable or metastatic urothelial cancer after platinum-containing chemotherapy** Nivolumab is not recommended, within its marketing authorisation, for treating locally advanced unresectable or metastatic urothelial carcinoma in adults who have had platinum-containing therapy. **No action required** **TA 531 Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer** Pembrolizumab is recommended as an option for untreated PD-L1-positive metastatic non-small-cell lung cancer (NSCLC) in adults whose tumours express PD-L1 (with at least a 50% tumour proportion score) and have no epidermal growth factor receptor- or anaplastic lymphoma kinase-positive mutations, only if: • pembrolizumab is stopped at 2 years of uninterrupted treatment or earlier in the event of disease progression and • the company provides pembrolizumab according to the commercial access agreement. **Resource impact:** This technology is commissioned by NHS England **Action:** The formulary entry for pembrolizumab will be updated with a link to NICE TA 531. **TA 532 Cenegermin for treating neurotrophic keratitis** Cenegermin is not recommended, within its marketing authorisation, for treating moderate or severe neurotrophic keratitis in adults. **No action required** **TA 533 Ocrelizumab for treating relapsing–remitting multiple sclerosis** Ocrelizumab is recommended as an option for treating relapsing–remitting multiple sclerosis in adults with active disease defined by clinical or imaging features, only if: • alemtuzumab is contraindicated or otherwise unsuitable and • the company provides ocrelizumab according to the commercial arrangement. **Resource impact:** This technology is commissioned by NHS England **Action:** Ocrelizumab will be added to the area prescribing formulary as RED with a link to NICE TA 533. **NG 99 Brain tumours (primary) and brain metastases in adults** This guideline covers diagnosing, monitoring and managing any type of primary brain tumour or brain metastases in people aged 16 or over. It aims to improve diagnosis and care, including standardising the care people have, how information and support are provided, and palliative care.	

	Resource impact: commissioned by NHS England **Action:** For information **NG100 Rheumatoid arthritis in adults: management** This guideline covers diagnosing and managing rheumatoid arthritis. It aims to improve quality of life by ensuring that people with rheumatoid arthritis have the right treatment to slow the progression of their condition and control their symptoms. People should also have rapid access to specialist care if their condition suddenly worsens. **Resource impact:** no impact anticipated **Action:** For information **NG 101 Early and locally advanced breast cancer: diagnosis and management** This guideline covers diagnosing and managing early and locally advanced breast cancer. It aims to help healthcare professionals offer the right treatments to people, taking into account the person's individual preferences. **Action:** local guidance to be reviewed. Recommendation to use sodium clodronate or zolendronic acid in place of other bisphosphonates may impact local resources. **NICE August Fast track guidance** **TA 534 Dupilumab for treating moderate to severe atopic dermatitis.** Dupilumab is recommended as an option for treating moderate to severe atopic dermatitis in adults, only if: • the disease has not responded to at least 1 other systemic therapy, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or these are contraindicated or not tolerated • the company provides dupilumab according to the commercial arrangement. **Resource impact:** Dupilumab is a high cost drug commissioned by CCGs The list price of two 300mg pre-filled syringes is £1264.89 (ex VAT). The average cost per patient based on this list price is £18087.91 in year one and £16443.70 from year two onwards based on the list price and homecare dispensing from week 13. A PAS discount has been agreed as a condition of the TA recommendation. **Action:** Dupilumab will be added to the formulary for prescribing in line with the recommendations in TA 534. Prescribing will remain with dermatology specialists with the expectation that the product will be made available via homecare from 13 weeks. The formulary entry will be RED hospital prescribing only.	JW/CW
4.18.6.5	**EAMS** None received	
4.18.6.6	**DPC update** The minutes from the June DPC meeting were noted. MEC notes were not received.	

4.18.6.7	**Southern Health medicines management update** VL provided an update. There was a recent update with small amendments to bipolar guidelines. Gosport War Memorial report was discussed. There will be a formal response from SHFT/Solent and PHT regarding the report findings. It was noted that there are current difficulties around the prescribing of syringe drivers. Current recommendations that are supported by the palliative care team is that patients should not be prescribed syringe drivers prior to receiving opioids to ensure that care is individualised to the needs of the patient. In addition, Southern Health, Solent, and PHT commented that they will be running the ADIoS report	
4.18.6.8	**Solent medicines management update** JE provided an update. There is ongoing work to review and update a number of guidelines. Many of these have been previously co-badged with SHFT. There is a desire to encourage joint working of SHFT and Solent which is supported by the APC.	
4.18.6.9	**Priorities committee update** Priority Statement 35 - Sequential use and Dose Escalation of Biologic therapy in the Management of Psoriasis SC presented the priorities committee statement following it's submission to the CSC. There were concerns raised that there is poor evidence base for the recommendation, the statement does not restrict use and this may have an impact on local resources. The CSC request that there is a prior approvals process in place.	
4.18.6.10	**Hampshire Medicines Safety Group** The minutes of the July meeting were noted. PF presented having attended the meeting. There has been local problems with methotrexate injections. Patients have been inadvertently supplied with a different brand due to generic prescribing. The concern is that the device may be different to what the patient had been trained to use and that one of the devices does not fit in the sharps bin for safe disposal. The CCG teams are working with the specialists to resolve these issues but there is ongoing work to be done. CD accountable officer changes in the locality. A representative from Rowlands declined to attend the meeting. They had been invited to attend to discuss concerns raised around the new MDS system they had proposed to use. APC members noted that they had received communication that a number of branches had been closed due to staff shortages. This has been reported to NHS England. There were also discussions about the changes to Rowlands process for MDS prescriptions. When changes have been made to patient medication the pharmacy require two weeks notice, this has impacted on PHT pharmacy. The national contract stipulates that on discharge from hospital only one week on MDS medication needs to be supplied.	

4.18.6.11	**Drug Safety Update and Patient Safety Alerts** June: • Dolutegravir: signal of increased risk of neural tube defects; do not prescribe to women seeking to become pregnant; exclude pregnancy before initiation and advice effective contraception • Denosumab (Xgeva) for giant cell tumour of bone: riak of clinically significant hypercalcaemia following discontinuation • Denosumab (Xgeva) in advances malignancies involving bone: study data show new primary malignancies reported more frequently compared to zoledronic acid July: • Darunavir boosted with cobicistat: avoid use in pregnancy due to risk of treatment failure and maternal-to-child transmission of HIV-1 • Pressurised metered dose inhalers: risk of airway obstruction from aspiration of loose objects • Eltrombopag: reports of interference with bilirubin and creatinine test results • Parenteral amphotericin B: reminder of potentially fatal adverse eaction if formulations confused • Medicines taken during pregnancy: please report suspected adverse drug reactions, including in the baby or child, on a Yellow Card August: • Esmya – restrictions to use **Action required** The APC have changed the formulary status of Esmya to RED (hospital prescribing only). JW to inform gynaecology department	JW
4.18.6.12	**Regional Medicines Optimisation Committees** **London RMOC update July 2018** Summary noted. **Insulin safety** RMOC has recommended changes to the application process for area prescribing committees for insulin to encourage safe practice. Action required: JW to review guidance and produce an updated application form for insulin formulary submissions. **Best value biologics** The document was noted by APC. A framework is expected in December with changes to prescribing practice from January/February. Concerns noted around the capacity of homecare providers. **Free of charge medication schemes** The document was noted by APC committee members. It is in support of the APC and PHT approach to FOC schemes. **Items which should not be routinely prescribed in primary care** Targinact was discussed as it is listed within the NHS England document as an item not to be routinely supplied in primary care. The 2014 business case for Targinact was reviewed.	JW

	APC decision: Targinact may continue to be included on the area prescribing formulary as Amber initiated. The APC noted that the only approved indication for use is for patients with opioid induced intestinal failure. JW will feed back this restricted use to Gastroenterology.	JW
4.18.7	**Any other business:** **Budenofalk use** JW discussed a short business case for Budenofalk Rectal Foam following the long term supply problems of Colifoam. Budenofalk foam enema had been discussed at the FMG group in March and was accepted on to the formulary as Red. The use of Budenofalk presents a cost pressure to the local health economy of approximately £20k per year. APC decision Budenofalk may be used as a second line option whilst alternatives are not available. Formulary status will be reviewed in 6 months. Budenofalk's formulary status will be amended to Amber recommended. **Shared care agreements** JW also requested support from the APC to encourage the review of out of date shared care agreements. Out of 30 published documents only 5 are currently in date. APC support the timely review of shared care agreements for use in the local area and are keen to encourage the principles of the latest NHS England document, responsibility for prescribing between primary and secondary care, are implemented. The APC will notify departments of out of date shared care agreements and send them a copy of the NHS England document.	JW
4.18.8	**Dates of future meetings:** **Friday October 19th 2018** **Friday December 14th 2018** **Submission deadlines for APC meetings:** Wednesday 10th October for October meeting Friday 30th November for December meeting	