

## **DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)**

### **Minutes of the meeting held on Tuesday 8<sup>th</sup> April 2014**

## **CONFIRMED MINUTES**

### **Summary Points**

#### **Traffic lights**

<b>Drug</b>	<b>Decision</b>
Canagliflozin	Not yet classified (await update of local type 2 diabetes guideline)
Dapagliflozin + Metformin (Xigduo)	BLACK
Tamsulosin + Solifenacin (Vesomni)	BLACK
Blephaclean and similar related products	BLACK
Co-Proxamol	BLACK
Aflibercept	BLACK (as per TA307 for metastatic colorectal cancer)
Rituximab	RED (as per TA 308 rituximab in combination with glucocorticoids for treating antineutrophil cytoplasmic antibody-associated vasculitis)
<b>Medical device</b>	<b>Decision</b>
TheraBite Jaw Device	RED
TheraBite Bite Pads	GREEN after specialist initiation following head & neck cancer treatment only
Debrisoft	RED

#### **Clinical Guidelines**

Nebuliser guidelines for people with COPD

#### **Misc**

Medical Devices and Appliances – principles for prescribing

<b>Present:</b>	
<b>Southern Derbyshire CCG</b>	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Professional Secretary)
Mr S Hulme	Director of Medicines Management
Dr I Tooley	GP
<b>North Derbyshire CCG</b>	
Dr C Emslie	GP
Dr D Fitzsimons	GP
Mrs K Needham	Head of Medicines Management North (also representing Hardwick CCG)
<b>Hardwick CCG</b>	
Dr T Parkin	GP
<b>Erewash CCG</b>	
Dr M Henn	GP
<b>Derbyshire County Council</b>	
Dr E Rutter	Public Health Consultant
Mrs S Qureshi	NICE Audit Pharmacist
<b>Derby Hospitals NHS Foundation Trust</b>	
Dr W Goddard	Chair – Drugs and Therapeutics Committee
<b>Derbyshire Healthcare NHS Foundation Trust</b>	
Dr S Taylor	Chair – Drugs and Therapeutics Committee
<b>Chesterfield Royal Hospital NHS Foundation Trust</b>	
Mr M Shepherd	Head of Medicines Management
<b>Derbyshire Community Health Services NHS Trust</b>	
Mr M Steward	Chief Pharmacist
<b>Healthwatch Derbyshire</b>	
Mr D Bailey	Lay Representative
<b>In attendance</b>	
Miss P Chera	Medicines Management Technician

Item		Action
1.	<b>APOLOGIES</b>	
	Dr C Shearer, Mr C Newman, Mrs L Hunter	
2.	<b>DECLARATIONS OF CONFLICT OF INTEREST</b>	
	After the last meeting a form was circulated for JAPC members to complete. Dr Mott asked for these to be completed.	
3.	<b>DECLARATIONS OF ANY OTHER BUSINESS</b>	
	None	
4.	<b>MINUTES OF JAPC MEETING HELD ON 11<sup>th</sup> MARCH 2014</b>	
	<p>The following amendments were made to the minutes of the meeting held on 11<sup>th</sup> March 2014:</p> <p><b>Page 3</b>            Compression stockings – amend to: <i>how <u>often</u> to replace stockings</i></p> <p><b>Page 5</b>            Alogliptin spelt incorrectly            Amend: <i>outcome date to outcome <u>data</u></i></p> <p><b>Page 6</b>            Alogliptin – amend to: <i>Alogliptin UNCLASSIFIED <u>pending updated diabetes guideline</u></i>            Relvar – <i>Propionate spelt incorrectly</i></p> <p><b>Page 7</b>            POTABA – <i>Peyronie’s spelt incorrectly</i></p> <p><b>Page 8</b>            Out of hours formulary – <i>amend EllaOne to generic name</i>            Shared care guidelines – <i>Sulfasalazine spelt incorrectly</i></p> <p><b>Page 10</b>            Actinic Keratosis – <i>Dr Bleiker spelt incorrectly</i></p> <p><b>Page 11</b>            Alcohol &amp; substance misuse – <i>action two to be changed to AM</i></p> <p>Subject to amendments stated, JAPC agreed they were happy to accept the minutes of the March 2014 meeting</p>	<p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p>
5.	<b>MATTERS ARISING</b>	
	<p><b><u>ADHD shared care guideline</u></b></p> <p>Mr Dhadli informed the group that there has been an exchange of e-mails regarding further clarity around the required monitoring necessary in children. Stating that monitoring of blood pressure and heart rate should be done by a specialist and not a GP. Dr Taylor referred to the current shared care which includes GP responsibilities for monitoring in primary care, which he thinks would be reasonable but it is about getting the logistics about two way communication very slick.</p> <p>Mr Dhadli added that the queries raised at the March JAPC meeting regarding the place of lisdexamfetamine, dosing for Dexedrine and the monitoring for children have been resolved.</p> <p>Dr Mott suggested that Dr Taylor should share concerns about monitoring in adults and follow up with Hardwick CCG prior to the ADHD shared care guideline being discussed again at the May JAPC meeting. Dr Parkin added that he has raised this with the Hardwick CCG commissioners.</p>	

Item	Action
<p><b>Lipid modification – NICE draft guideline</b>  <b>High intensity statins</b>            Dr Goddard informed the group there were no further comments</p> <p><b>Vacuum devices</b>            Mr Dhadli informed the group that Nottingham have three different classifications for vacuum devices:</p> <ol style="list-style-type: none"> <li>a. RED – for penile rehabilitation following radical prostatectomy</li> <li>b. AMBER2 – for non-post op patients who qualify under SLS criteria</li> <li>c. GREY – for all non SLS criteria</li> </ol> <p>Mr Dhadli went on to discuss the evidence for vacuum devices. It is well documented in NICE CG 175 for prostate cancer from January 2014, that vacuum pumps are an option following 1<sup>st</sup> line treatment with PDE5 inhibitors. Similarly stated and positioned in the European Association of Urology guidance 2013 as an option for patients that have undergone nerve sparing surgery. The British Society for sexual medicine suggests that vacuum pumps are highly effective, have good satisfaction rates and men can continue to use them longer. Mr Dhadli also informed the group of the safety concerns that were raised by the Nottinghamshire GP's, adverse effects included pain, inability to ejaculate, petechiae, bruising and numbness. Serious adverse effects included skin necrosis if the constriction ring is not removed within 30 minutes. Mr Dhadli added that the BSSM guidance states that pumps work better if sufficient time has been spent demonstrating their use.</p> <p>The Nottinghamshire proposal discussed the vacuum pumps not included in tariff and the other variation Mr Dhadli noted was that vacuum pumps + PDE5 inhibitors are used together for seven weeks soon after surgery for which there is little evidence.</p> <p>Mr Dhadli had asked Royal Derby Hospital and Chesterfield Royal Hospital to provide a patient pathway. In its absence stated that Nottinghamshire patients are seen every four months for the first year where sexual function is part of the review.</p> <p>The cost of the pumps range from £98 to £191 and the constrictor rings vary in pack and ring size with the cost being between £4 and £17 and last for approximately eight uses.</p> <p>Mr Dhadli added that the aim of treatment is for a cure following radical prostatectomy and that the BSSM suggests the duration of treatment with vacuum pumps is long term however the literature suggests that where patients have had a nerve sparing procedure improvement may take up to two years.</p> <p>Dr Mott reminded the group that the background to this was to have some consistency. Mr Shepherd informed the group that he is due to meet with the urologists at CRH to discuss these devices. Dr Goddard informed the group that there had been brief discussions about vacuum devices outside of the D&amp;T committee meeting and that he was not aware of any precise protocols.</p> <p>Mr Dhadli added that what is in or out of tariff is not a debate that should be had. The proposal in Nottinghamshire was made because the vacuum devices were not in-tariff and this was the reason GPs were being asked to prescribe. Dr Mott added that the system in Nottinghamshire seems complicated and that locally it is about who provides the devices and who is responsible for prescribing going forward.</p> <p><b>Agreed:</b> Dr Mott asked that both CRH &amp; RDH provide JAPC with the following to enable the group to classify the device and rings appropriately:</p> <ol style="list-style-type: none"> <li>a. What the urologists currently do</li> <li>b. Number of patients expected to be treated</li> </ol>	<p style="text-align: right;"><b>CRH/RDH</b></p>

Item		Action
	c. Patient pathway d. What the clinics would prefer to happen	
6.	<b>NEW DRUG ASSESSMENTS/TRAFFIC LIGHT ADDITIONS</b>	
	<p><b><u>TheraBite</u></b>            Mr Shepherd presented a paper produced by the speech &amp; language therapy team at CRH in collaboration with the RDH. The paper sets out the background into why these are used, evidence to support their use and the costs of the device. JAPCs preferred option is that TheraBite will be initiated by the speech &amp; language department but the on-going supply of pads will be made via the GP.</p> <p><b>Agreed:</b> TheraBite device classified as <b>RED</b></p> <p><b>Agreed:</b> Bite pads classified as <b>GREEN after specialist initiation following head &amp; neck cancer treatment only</b></p> <p><b>Agreed:</b> To include a statement in the traffic light database that 4 Bite pads would last 6 months.</p> <p><b><u>Canagliflozin</u></b>            Mr Dhadli informed the group that canagliflozin has been identified in this month's new product bulletin. It is the second SGLT2 inhibitor being considered by JAPC, the first being dapagliflozin. Canagliflozin works by enhancing the urinary glucose secretion.</p> <p>Mr Dhadli reminded the group that dapagliflozin was covered by the NICE TA 288 and JAPC classified this as brown after specialist initiation based on the renal effects, contraindications, the lack of long term data, reports about genital and/or urinary tract infections and breast and bladder cancer.</p> <p>Mr Dhadli informed the group that canagliflozin is undergoing a NICE TA which is expected in June 2014. It has a slightly different indication to dapagliflozin as it is recommended for triple therapy; it has two strengths and two different costs. Canagliflozin is initiated at 100mg and titrated to 300mg to achieve the desired effect with the lower dose dependent upon renal disease.</p> <p>Mr Dhadli added that the drug is supported by evidence from the CANTATA studies, one of which compares canagliflozin to sulfonylureas and also one with insulin and pioglitazone. Evidence that relates to HBA1c reductions demonstrating efficacy.</p> <p>Mr Dhadli suggested that the group should either consider leaving this drug unclassified until the NICE TA is available or to classify as black to deal with any requests that might be received for prescribing in primary care. Mr Dhadli added that a NICE TA for a third SGLT2 inhibitor called empagliflozin is also expected in December 2014.</p> <p>Dr Goddard questioned whether this formed part of the review of the local diabetes guideline to which Mr Dhadli added that it was unclear if the authors of the new guideline were looking at these new drugs.</p> <p><b>Agreed:</b> Canagliflozin <b>NOT YET CLASSIFIED pending update of local diabetes guideline</b></p> <p><b><u>Dapagliflozin plus metformin (Xigduo)</u></b>            Mr Dhadli asked JAPC to consider whether combination products should be classified at the same time that individual components are classified. Mr Dhadli listed the advantages and disadvantages of this particular product:            Advantages:</p>	<p><b>SD</b></p> <p><b>SD</b></p> <p><b>SD</b></p> <p><b>SD</b></p> <p><b>SD</b></p>

Item		Action
	<ul style="list-style-type: none"> <li>• Improve patient compliance</li> <li>• Cost neutral when added to metformin</li> </ul> <p>Disadvantages:</p> <ul style="list-style-type: none"> <li>• Does not allow titration of metformin to maximum BNF dose of 2g or locally agreed dose used in trial of 3g</li> <li>• BNF also recognises TDS as dosing regimen</li> <li>• Could lead onto more add-on treatments if the dapagliflozin response is sub therapeutic (&lt;0.5% HbA1c at 6 months)</li> </ul> <p>Dr Mott added that in his opinion the only place a combination product might be suitable is if patients happen to be on these agents separately, there may then be some logic in them using combination products. Dr Mott added that this would be a handful of patients as dapagliflozin is a rarely used drug.</p> <p>Mr Dhadli raised concerns about other combination products becoming available some of which the individual components have previously been classified by JAPC. Mr Dhadli questioned whether JAPC should go back to these decisions or whether combination products are classified separately.</p> <p>Discussion followed and the group felt that if this is not given a traffic light classification some GPs may prescribe.</p> <p><b>Agreed:</b> Dapagliflozin plus metformin classified as <b>BLACK</b></p> <p><b><u>Tamsulosin plus solifenacin (Vesomni)</u></b></p> <p>Mr Dhadli informed the group that this is now a combination product of an alpha-blocker and an anticholinergic (tamsulosin 400mcg plus solifenacin 6mg). The combination treatment is recognised within NICE CG 97 section 1.4.7 which states 'consider offering an anticholinergic as well as an alpha-blocker to men who still have storage symptoms after treatment with an alpha-blocker alone'. Mr Dhadli went on to add that this is the only combination product with an alpha-blocker and anticholinergic and cheaper than its individual components. However further noted to JAPC that these are not first line choices and cheaper individual drugs existed.</p> <p>Mr Hulme questioned why the dose for solifenacin was 6mg. Mr Dhadli added that 6mg and 9mg doses were looked at in the NEPTUNE study so when transferring from individual components it may not be an equivalent dose.</p> <p>Dr Mott added that this isn't a secondary care drug so a red classification would not be appropriate, so suggested either black as it is not consistent with the drugs and dosing currently in use or brown to aid compliance.</p> <p><b>Agreed:</b> Tamsulosin plus solifenacin classified as <b>BLACK</b></p> <p><b><u>Blephaclean</u></b></p> <p>Dr Parkin informed the group that he has had two prescribing requests for blephaclean by opticians. Dr Parkin added that blephaclean is recommended for the daily hygiene of eyelids however it is expensive. JAPC noted that symptoms of blepharitis can usually be controlled with adequate self-help measures.</p> <p>Discussion followed around how opticians could be informed of decisions made by JAPC. Dr Mott suggested this should be picked up outside of the meeting.</p> <p><b>Agreed:</b> Blephaclean and similar related products classified as <b>BLACK</b></p>	<p style="text-align: right;"><b>SD</b></p> <p style="text-align: right;"><b>SD</b></p> <p style="text-align: right;"><b>SD</b></p>

Item	Action
<p><b><u>Rivaroxaban</u></b></p> <p>Mr Shepherd informed the group that he and his colleagues at CRH felt that locally we are becoming a little out of line in terms of our use of the Newer Oral Anticoagulants (NOACs) and the current restrictions particularly around AF mean that there are a significant number of patients who are being managed sub-optimally. Mr Shepherd added that the proposal is to give rivaroxaban a green after specialist initiation classification so that it can be initiated in line with its product license of both AF and treatment of VTE in those patients where warfarin might not be appropriate. Mr Shepherd also added that new NICE guidance for AF is due later this year which is likely to lead prescribers in this direction.</p> <p>Mrs Needham felt that rivaroxaban should be green and not green after specialist initiation. Mrs Needham added that for AF patients on sub-optimal treatment that perhaps primary care would like to have the chance to review patients and have that discussion rather than automatically being put on rivaroxaban whilst in hospital. Mrs Needham also added that a number of practices are currently looking at patients via GRASP-AF, so hopefully patients on sub-optimal treatment will be resolved going forward.</p> <p>Mr Dhadli informed the group that in the new draft NICE AF lists all NOACs as treatment options as per technology appraisals alongside warfarin and states that aspirin has no place in the treatment of AF.</p> <p>Mr Hulme shared some prescribing data for NOACs use within Southern Derbyshire CCG. Chart one shows the distribution of cost per patient, which shows a large distribution some of which is because the County practices do their own INR monitoring and initiation of warfarin. Chart two is a growth chart which is showing quite considerable growth of NOAC prescribing. The final chart shows the spend on NOACs for Southern Derbyshire. This shows roughly around 500 to 600 items are used of NOACs compared to 6000 to 7000 for warfarin, but the costs of NOACs are half that of the warfarin which gives an indication of where the costs are going. Mr Hulme added that when making decisions about the use of NOACs the group should consider affordability. Mrs Needham added that by not changing practice, GPs and patients are being left in a difficult position. Dr Mott went on to add that some GPs are not following the current local guidelines, some of which are open to challenge. This may be due to accessing scans for DVT, use of heparin and use of district nurse time, which is more expensive than NOACs. Dr Mott added that if we are adding onto our prescribing spend then money should follow to the appropriate budget e.g. the local enhanced service for monitoring warfarin.</p> <p>Discussion followed around the appropriate classification for rivaroxaban. The general consensus of the group was that although there is a significant cost pressure with the use of NOACs there does need to be another option for GPs to prescribe where warfarin or aspirin are not appropriate.</p> <p>Dr Henn at this point declared an interest as he works in a practice where anticoagulation monitoring is beyond the practice boundary. Dr Henn added there is a clinical argument for the use of rivaroxaban and it could aid compliance, however he raised concerns that some prescribers may see this as an easy option. Dr Henn felt that GPs should be reminded that patients on NOACs should be monitored just as much as they would if they were on warfarin.</p> <p>Mr Dhadli added that the original plan was to gain experience with a preferred NOAC (rivaroxaban) and set the time in therapeutic range to a low value targeting those poorly controlled on warfarin first. As experience grew and safety emerged then this would be reviewed.</p> <p>Mr Hulme questioned whether safety data should be checked with the MHRA now that</p>	

Item		Action
	<p>there is more use of the NOACs.</p> <p><b>Agreed:</b> CRH &amp; RDH to work together to re-draft the AF guidance</p> <p><b>Agreed:</b> Check safety data for NOACs</p>	<p><b>MS</b></p> <p><b>SD</b></p>
7.	<b>CLINICAL GUIDELINES</b>	
	<p><b><u>Managing behaviour problems in patients with dementia</u></b></p> <p>Dr Taylor informed the group that this is an update of an existing guideline. The changes are based on some extra evidence. Dr Taylor added that some studies have been published showing negative effects of medication causing harm particularly with strokes, falls and only one positive study looking at the anticholinergics in Parkinson's disease. The changes include:</p> <ul style="list-style-type: none"> <li>• In the flow-diagram in box 1 highlighting haloperidol</li> <li>• Sertraline downgraded to 2<sup>nd</sup> line for depression category and added to 2<sup>nd</sup> line for moderate agitation category in SDAT to fit current evidence</li> <li>• Added to box 1 a falls reminder with SSRI and some information regarding the need for individualised risk/benefit assessment</li> <li>• Rivastigmine moved to 1<sup>st</sup> line for Parkinson's disease dementia</li> <li>• Highlighted the limited amount of evidence for interventions</li> </ul> <p>Mr Dhadli added that the evidence around greater mortality data with haloperidol is supported by new articles published in the BMJ and the American Journal of Psychiatry. Mr Dhadli queried the demotion of sertraline and questioned what evidence source had been used as he was unable to find this but did note that in 2012 there were queries around dose related falls with SSRIs but not a particular SSRI. Mr Dhadli also added that the use of Rivastigmine 1<sup>st</sup> line for Parkinson's disease dementia and dementia with Lewy Bodies is backed by a Cochrane review.</p> <p>Dr Mott also raised concern about the demotion of sertraline and citalopram becoming 1<sup>st</sup> line agents due to recent warnings around interactions and QT interval prolongation. Dr Mott added that it would be useful to understand the recommendation for citalopram to be used 1<sup>st</sup> line more clearly.</p> <p>Mr Dhadli added that there are two preparations for rivastigmine; it would be useful to clarify if normal release or the XL should be used. The latter being significantly more expensive.</p> <p>Mrs Needham added that zopiclone is now the preferred agent in primary care for poor sleep and questioned whether the guideline could recommend this rather than include the option of temazepam.</p> <p>Mr Hulme questioned whether something could be included in the guideline about what proportion of patients with dementia could be managed without antipsychotic drugs as this could give a benchmark to establish whether patients are being treated appropriately. Dr Mott added that a recent parliamentary review indicated that harm can be caused by these drugs.</p> <p><b>Agreed:</b> Dr Taylor to discuss the recommendation to demote sertraline to 2<sup>nd</sup> line and the recommendation to use citalopram 1<sup>st</sup> line with DHCFT colleagues</p> <p><b><u>Nebuliser guideline for COPD</u></b></p> <p>Mr Dhadli informed the group that this is an update of existing guideline. This has been out for consultation and has been to the guideline group.</p> <p>Mrs Needham suggested that the front page should be updated to indicate that this is a Derbyshire wide guideline.</p>	<p><b>ST</b></p>



Item		Action
	<p>Mr Hulme questioned whether the guideline was just for assessing and initiating new patients or whether existing patients on nebulisers are reviewed through this service. Mr Dhadli confirmed that the guideline is purely for assessing and initiating nebulisers in new patients. Discussion followed and the group felt that existing patients on a nebuliser who have never had a formal assessment should be referred into the service.</p> <p>Mr Bailey asked if the guideline had been reviewed by any patient groups and added that it is well proven in certain areas that nebulisers can be bad for people with COPD. Mr Bailey also raised concern about patients not being reviewed. Dr Mott explained that the purpose of the guidance is to ensure GPs do not inappropriately initiate nebulisers and to ensure that there is a clear process for patients to be formally assessed.</p> <p>Mr Hulme added that the title of the guideline is misleading and felt that it should be specific about what it is.</p> <p>Dr Henn added that in the past the respiratory nurses have been happy to do specific nebuliser assessments for patients already on nebulisers who hadn't had an assessment. Dr Henn added that the respiratory nurses felt it was within their remit to ensure patients on nebulisers know how to use them and are using them as recommended. Dr Mott added that he would like to include something about referring into the service if patients have never previously been assessed or GPs have concerns about the use of nebulisers.</p> <p>Dr Henn also added that the benefit of nebulisers over MDIs with spacers is minimal to non-existent and there are not many clinical reasons why it changes apart from patients not at all being able to use the MDI with a spacer. Dr Henn added that some patients won't need re-assessment but it would be helpful to include patients who might have acquired nebulisers themselves and also patients who may have been initiated on a nebuliser elsewhere where procedures might be lacking. Dr Henn explained that from his experience the respiratory nurses have been more than happy to reduce the inappropriate use of nebulisers.</p> <p><b>Agreed:</b> Front sheet to be changed to JAPC format</p> <p><b>Agreed:</b> Confirm with the respiratory nurses if patients on nebulisers who have not had a formal assessment can be referred into the service and if patients can be re-assessed if GPs have concerns about nebuliser use</p> <p><b>Agreed:</b> Title to be changed to Derbyshire nebuliser guideline for COPD – assessment &amp; initiation</p> <p><b>Agreed:</b> Guideline ratified pending minor amendments</p>	<p>SD</p> <p>SD</p> <p>SD</p>
8.	<b>PGDs</b>	
	None	
9.	<b>SHARED CARE GUIDELINES</b>	
	<b><u>Acamprosate &amp; Disulfiram</u></b> Deferred to the May meeting	
10.	<b>HORIZON SCAN</b>	
	<p><b><u>Monthly horizon scan</u></b></p> <ul style="list-style-type: none"> <li>• Alogliptin and alogliptin plus metformin – discussed last month</li> <li>• Canagliflozin – discussed under agenda item 6</li> <li>• Dapagliflozin plus metformin – discussed under agenda item 6</li> <li>• Tamsulosin plus solifenacin – discussed under agenda item 6</li> </ul>	
11.	<b>MISCELLANEOUS</b>	

Item	Action
<p><b><u>Alcohol commissioned services for Derby City</u></b>            Dr Mott informed the group that he and Mr Dhadli met with Public Health in Derby City. Dr Mott added that there is a gap in the service; they are looking to re-commission their alcohol services. There is a current bridging provision which leaves things unchanged from a prescribing point of view. Concerns were raised at the last JAPC meeting about the shared cares being invalid because there may not be anyone in the service who could initiate and prescribe them however Dr Mott confirmed that this is not the case and that where prescribing is required there is still an arrangement in place with DHcFT.</p> <p><b><u>Co-proxamol</u></b>            Mr Dhadli informed the group that JAPC previously classified co-proxamol as brown recognising that there was some historic prescribing. Mr Dhadli added that the guideline group have made a recommendation for co-proxamol to be re-classified to black based on a decision that was made some time ago.</p> <p>Mr Dhadli shared some prescribing data which indicates that prescribing is low however there are pockets of practices that may not have tackled the issue.</p> <p><b>Agreed:</b> Co-proxamol classified as BLACK</p> <p><b><u>Early Access to Medicines Scheme (EAMS)</u></b>            Mr Dhadli informed the group that the government has announced a new scheme which aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation. Mr Dhadli added that the MHRA have introduced a two-step evaluation process:</p> <ul style="list-style-type: none"> <li>• Step 1 is applicable where the medicine for treatment is for promising innovative medicines designation. Trial data from phase II and phase III studies recognise this would be to treat life threatening or seriously debilitating conditions where there is an unmet need, where the benefits outweigh the risks and where the UK economy would benefit from the scheme. Drugs they would recognise are new biological or chemical entities but also re-purposing of established or recently approved drugs which will include cancer drugs</li> <li>• Step 2 is the early access to medicines scientific opinion. The MHRA will issue a new benefit to risk opinion to support the prescriber</li> </ul> <p>After completing the above the MHRA would consider licensing and rapid commissioning which would be introduced through a NICE technology appraisal, the manufacturers would negotiate with the PPRS or patient access scheme to adjust the value proposition and only when it is licenced it will typically be commissioned by NHS England through its specialised commissioning arrangements.</p> <p>Mr Dhadli added that USA has a similar system in place called 'breakthrough therapy' designation. Mr Dhadli went on to say that the MHRA envisage that there will be two products per year that will be granted an opinion under the scheme based on preliminary data from the industry but the respondents to the consultation cite five to twelve drugs and the government has stated that there will be no limit to these. Most of the drugs will be identified after the phase III studies but could be eligible after phase II on occasion. The MHRA will continue to monitor the drugs through the yellow card system.</p> <p>Mrs Needham questioned who paid for the drugs to which Mr Dhadli responded that the drugs will be provided for free however once the drug gets a license, there would be a NICE technology appraisal, a reasonable price would be worked out and NHS England will commission the drugs but this could possibly be CCGs.</p> <p><b><u>Medical devices and appliances – principles for prescribing</u></b>            Mr Hulme informed the group that he has produced some guidance outlining principles</p>	<p><b>SD</b></p>

Item		Action
	<p>to determine JAPC traffic light classification for medical devices and appliances which may be prescribed on FP10. Mr Hulme added that this document follows what we would normally do around making decisions about drugs such as using JAPC templates for new requests, consider best available evidence using the Barber's Box criteria: safety, effectiveness, patient factors and cost, consider clinical competencies to prescribe and traffic light classifications.</p> <p><b>Agreed:</b> Guidance ratified</p> <p><b><u>MTRAC</u></b>            Mr Dhadli informed the group that the MTRAC commissioning support guidance's are for information. The first guidance was about Denosumab for which there is already a shared care agreement in place. Mr Dhadli added that the review reflects what is already happening locally however it does recommend a referral back to secondary care at three years but the shared care agreement locally recommends five years. Mr Dhadli checked the All Wales guidance which recommends five years and also the SPC which doesn't specify so felt that five years locally was acceptable.</p> <p>The second guidance was about the combination product, fluticasone furoate plus vilanterol. Mr Dhadli added that this was discussed and classified at the last JAPC meeting.</p> <p>The final commissioning support guidance was about rifaximin for treating overt hepatic encephalopathy. Mr Dhadli added that MTRAC considered that rifaximin was suitable for prescribing in primary care, following initiation and stabilisation in secondary care under a shared care agreement. Mr Dhadli went on to add that JAPC have discussed the classification of rifaximin previously and because there is no monitoring felt that the classification of 'green' after specialist initiation was appropriate. There is also a NICE TA expected on this but still no date.</p>	
12.	<b>JAPC BULLETIN</b>	
	<p><b><u>Fluticasone</u></b>            Fluticasone spelt incorrectly in the title</p>	SD
13.	<b>MHRA DRUG SAFETY UPDATE</b>	
	<p><b><u>Monthly MHRA newsletter</u></b>            Mr Dhadli highlighted the safety advice given in the drug safety update about orlistat and its theoretical interaction with antiretroviral HIV medicines and St John's wort and its interaction with hormonal contraception which now includes implants. Mr Dhadli informed the group that he has included these in this month's medicines management newsletter. BNF formulary chapter seven has been updated to include information about St John's wort and its interaction with hormonal contraception.</p> <p><b><u>Patient safety alerts</u></b>            Mr Hulme informed the group that NHS England and the MHRA are working together to simplify and increase reporting, improve data quality, maximise learning and guide practice to minimise harm by producing patient safety alerts. Mr Hulme added that summaries of two alerts have been shared but the more detailed documents, outline that there should be a safety panel which pulls together various providers within the health community and commissioners to share learning and agree action plans. It also outlines what the provider responsibilities are and how incidents should be reported upwards. The document also states that commissioners should be invited to participate.</p> <p>Dr Mott added that there are some for general practice for CCGs to consider around advertising more and raising awareness of GP responsibilities.</p>	SD
14.	<b>NICE TEMPLATE</b>	
	<b><u>Framework of NICE Guidance</u></b>	

Item		Action
	<p>Mrs Qureshi informed the group of the comments of the CCGs which had been made for the following NICE guidance issued in March:</p> <p>TA307 Aflibercept in combination with irinotecan and fluoracil-based therapy for treating metastatic colorectal cancer that has progressed following prior oxaliplatin-based chemotherapy            Mrs Qureshi informed the group that this treatment is not recommended.</p> <p><b>Agreed:</b> Aflibercept classified as BLACK as per NICE TA307</p> <p>TA308 Rituximab in combination with glucocorticoids for treating antineutrophil cytoplasmic antibody-associated vasculitis            Mrs Qureshi informed the group that NICE has recommended that this drug is commissioned via NHS England and suggested a traffic light classification of RED.</p> <p><b>Agreed:</b> Rituximab classified as a RED drug as per NICE TA308</p> <p>Mr Dhadli informed the group that the framework includes an MTG for Debrisoft for use in acute or chronic wounds. Mr Dhadli added that MTGs are not mandatory however he did have a look at it and asked for comment from the tissue viability nurses. Mr Dhadli also added that NICE do recommend this but the evidence is weak, there are no randomised controlled studies, there are fifteen multiple patient case report series, ten of which are posters, there is lack of good quality comparative data, but does specify where it would be used. There is small evidence for use in sloughy wounds with exudate and hyperkeratotic skin however it is not cost effective if having to use more than nine applications in clinical practice or more than ten in a home.</p> <p>Mr Dhadli also added that the poor evidence is recognised by the tissue viability nurses who wouldn't recommend this as first line. The tissue viability nurses discarded this previously due to cost and evidence. The tissue viability nurses would like to use this second line. Dr Mott suggested a classification of black or red. Mr Steward added that he wouldn't expect this to be used first line but would expect it only to be used rarely and after specialist initiation.</p> <p><b>Agreed:</b> Debrisoft classified as RED as per MTG17</p>	<p><b>SD</b></p> <p><b>SD</b></p> <p><b>SD</b></p>
15.	<b>TRAFFIC LIGHTS – ANY CHANGES?</b>	
	<p>TheraBite Jaw Device – <b>RED</b>            TheraBite Bite Pads – <b>GREEN after specialist initiation</b>            Canagliflozin – <b>Not yet classified (await update of local type 2 diabetes guideline)</b>            Dapagliflozin + Metformin (Xigduo) – <b>BLACK</b>            Tamsulosin + Solifenacin (Vesomni) – <b>BLACK</b>            Blephaclean and similar related products – <b>BLACK</b>            Co-Proxamol – <b>BLACK</b>            Aflibercept – <b>BLACK as per NICE TA307</b>            Rituximab – <b>RED as per NICE TA308</b>            Debrisoft – <b>RED as per NICE MTG17</b></p> <p>Dr Goddard asked informed the group that Diazoxide was classified as hospital only at the RDH D&amp;T committee and questioned whether this should be included on the traffic lights. Dr Mott asked Dr Goddard to submit the paper to Mr Dhadli for consideration at the next JAPC meeting.</p>	<p><b>SD</b></p>
16.	<b>JAPC ACTION SUMMARY</b>	
	<p><b><u>Actinic Keratosis</u></b>            Mr Goddard informed the group that Dr Bleiker has sent an updated version of the guidance to colleagues in the North. This will be sent to the RDH D&amp;T committee and then submitted to the JAPC for ratification.</p>	

