Aylesbury Vale Clinical Commissioning Group
Bracknell and Ascot Clinical Commissioning Group
Chiltern Clinical Commissioning Group
Newbury and District Clinical Commissioning Group
North and West Reading Clinical Commissioning Group
Oxfordshire Clinical Commissioning Group
South Reading Clinical Commissioning Group
Slough Clinical Commissioning Group
Windsor, Ascot and Maidenhead Clinical Commissioning Group
Wokingham Clinical Commissioning Group

Thames Valley Priorities Committee
Minutes of the meeting held Wednesday 27th July 2016
Conference Room A, Oxfordshire CCG, Jubilee House, 5510 John Smith Drive, Oxford OX4 2LH

In Attendance:

Alan Penn	Lay Member Chair	Thames Valley Priorities Committee
Laura Tully	Clinical Effectiveness Lead	SCWCSU
Kathryn Markey	Clinical Effectiveness Manager	SCWCSU
Rachel Finch	Clinical Effectiveness Administrator	SCWCSU
Jane Butterworth	Associate Director of Medicines Management & Long Term Conditions	Aylesbury Vale CCG & Chiltern CCG
Dr Paul Harris	GP	Berkshire West CCGs
Catriona Khetyar	Head of Medicines Optimisation	Berkshire East CCGs
Professor Chris Newdick	Special Advisor – Health Law	University of Reading
Dr Will Orr (representing Lindsey Barker)	Consultant Cardiologist	Royal Berkshire NHS Foundation Trust
Sarah Robson	Head of IFR	SCWCSU
Jeremy Servian	IFR Manager	Oxfordshire CCG
Dr Ingrid Slade	Public Health Registrar, Special Advisor - Ethics	University of Oxford
Dr Karen West (representing Dr Graham Jackson)	Clinical Lead for Joint Commissioning and Partnership Working	Aylesbury Vale CCG
Sara Wilds (representing Linda Collins)	Head of Medicines Management	Oxfordshire CCG
Amy Wire (representing Minoo Irani)	Lead Pharmacist	Berkshire Healthcare NHS Foundation Trust
Cathy Winfield	Chief Officer	Berkshire West CCGs

Topic Specialists in Attendance for Agenda Items:

Dr Caroline Higgins	Consultant Dermatologist	Royal Berkshire NHS Foundation Trust
Dr Amal Eissa	Locum Consultant Dermatologist	Buckinghamshire Healthcare NHS Trust
Dr Malgosia Magliano	Rheumatology Consultant	Stoke Mandeville Hospital
Kate Russell Hobbs	Lead Pharmacist for Specialist Medicine	Buckinghamshire Healthcare NHS
Mr Kuan Sim	Consultant Ophthalmologist	Buckinghamshire Healthcare NHS Trust
Mr Tom Pollard	Consultant Orthopaedic Surgeon	Royal Berkshire NHS Foundation Trust

Mr Devendra Mahedevan	Consultant Orthopaedic Surgeon (Foot & Ankle)	Royal Berkshire NHS Foundation Trust

Apologies:

Heather Motion	Clinical Effectiveness Manager	South Central &West Commissioning Support Unit (SCSWCSU)
Tiina Korhonen	Clinical Effectiveness Lead	SCWCSU
Sarah Annetts	IFR Manager	SCWCSU
Lindsey Barker	Medical Director	Royal Berkshire NHS Foundation Trust
Dr Tony Berendt	Medical Director	Oxford University Hospitals NHS Trust
Miles Carter	West Oxfordshire Locality Clinical Director	Oxfordshire CCG
Linda Collins	NICE Lead	Oxfordshire CCG
Frances Fairman	Assistant Director – Clinical Strategy	NHS England TV Area Team
Dr Mark Hancock	Medical Director	Oxford Health NHS Foundation Trust
Minoo Irani	Medical Director	Berkshire Healthcare NHS Foundation Trust
Dr Graham Jackson	Clinical Chair	Aylesbury Vale CCG
Dr Megan John	GP	Bracknell and Ascot CCG
Tim Langran	Lead Support Pharmacist	Berkshire East CCGs
Dr Lise Llewellyn	Director of Public Health	Bracknell Forest Council
Tracey Marriot	Director of Innovation Adoption	Oxford Academic Health Science Network
Philip Murray	Chief Finance Officer	Chiltern CCG

1.0	**Welcome & Introductions**
1.1	The Chair opened the meeting and welcomed members of the Committee.
2.0	**Apologies for Absence**
2.1	Recorded as above. This meeting was declared quorate. An update around lay representation was given, the Thames Valley Healthwatch organisations have confirmed they are not able to prioritise sending a representative to attend the Committee meetings. **Action: Clinical Effectiveness team to consider future lay member representation.**
3.0	**Declarations of Interest**
3.1	None were declared.
4.0	**Draft Minutes of the Priorities Committee meeting held 25th May 2016 (Paper 16-072) – Confirm Accuracy** The following amendments were agreed: • Page 8 item 10.1, third paragraph – add text "prior to referral" for sentence to read "….**lifestyle advice also needed** to be included **prior to referral**" – CE Team to amend. • Page 8 item 10.1, third paragraph - amend "feedback" to "**fed back**" – CE Team to correct. • Page 8 item 10.1, fourth paragraph - remove 'time they' as it is repeated – CE Team to amend. • Page 8 item 10.1, fifth paragraph – add text "at what stage in care" for sentence to read "…around which tests need to be carried out, **at what stage in care** and whether this should be in primary or…." – CE Team to amend.
5.0	**Draft Minutes of the Priorities Committee meetings – Matters Arising**
5.1	Minutes of the Priorities Committee held in January 2016, Action 7.3 - Severe & complex obesity thresholds for surgery: Clinical Effectiveness team will review the draft scope and guidance and report at the 27th July 2016 meeting as planned. **Action Complete – refer to Agenda item 6.**
5.2	Minutes of the Priorities Committee held in May 2016, Action 6.4 – Verteprofin for Chronic Central Serious Chorioretinopathy: The Committee agreed to recommend use of verteporfin and PDT for IPCV and CSR within the criteria specified. The two conditions to be dealt with separately within the policy. Clinical Effectiveness (CE) team to prepare policy documents and circulate for comment with the meeting minutes. Comments to be received within the 2 week comment period following issue. **Action Complete.**
5.3	Minutes of the Priorities Committee held in May 2016, Action 7.5 – Sequential use of anti-VEGF treatment and steroid implants in ophthalmology: CE team to investigate further information around stopping criteria and local protocols around the conditions, particularly for DMO. **Action Complete – refer to Agenda item 9.**
5.4	Minutes of the Priorities Committee held in May 2016, Action 8.2 – Reflux surgery, withdrawal of local policies: CE team to provide a Governing Body paper to outline the proposed policy withdrawals for CCG agreement and action as per the usual process. **Action Complete.**
5.5	Minutes of the Priorities Committee held in May 2016, Action 9.1 – Use of biologic drugs for ulcerative colitis: CE team to draft a policy and circulate as per the usual process. **Action Complete.**
5.6	Minutes of the Priorities Committee held in May 2016, Action 10.1 – Fertility care pathway: 1). Dr Hussain to email a copy of her local flow chart to the CE team. 2). CE team to investigate the various providers' referral criteria and liaise with local GPs for further consultation. **Action Ongoing.**
6.0	**Paper 14-057 – Policy Update: Severe and Complex Obesity**
6.1	This topic was reviewed January 2016, following the NHS England decision to transfer the commissioning responsibility of severe and complex obesity and bariatric surgery back to the CCG's from April 2016. CCGs were awaiting further information from NHS England in order to

	project the demand for services, the service capacity and the affordability of the different threshold options with the information and data available. An interim policy in line with the NHS England policy was agreed with a review planned for the July 2016 meeting.
6.2	NHS England has proposed that the status quo is maintained for 2016/17 and has provided a service specification for 2017/18 which is in line with updated NICE CG189 (2014) criteria. Funding allocation following the transfer of commissioning responsibility to the CCGs is still to be determined.
6.3	It was noted that although the paper includes an indication of NICE's projected cost impact around the cost of implementation of the NICE CG guidance, it is likely to cost more as the estimates do not take into account the need to increase capacity in the lower obesity service tiers as well. The projection only indicates how much more it will cost for bariatric surgery. It was raised that IFR applications are starting to be received for Tier 3. Applications often do not meet the NHS England criteria which states patients need to have been obese for 5 years or more and CCGs are currently unable to control access to this service. It was suggested that the pathway needs to be tightened up. It was reported that the bariatric team in West Berkshire have a stringent screening system and therefore their conversion from Tier 3 into Tier 4 is about 80%. Their patients are not getting into Tier 3 service without meeting the referral criteria, giving the CCG some control over their funds and referrals. It was noted that there is a lack of clarity around whether CCGs or NHS England is currently responsible for Tier 3 services. The Committee discussed the variations across the Thames Valley as to how the pathways have evolved locally; there may be an opportunity to share them to provide some commonality and provide clarity for GPs. Patients in general should have attended Tier 1 & 2 obesity services prior to referral to Tier 3 with evidence of interventions undertaken. The Committee noted that without further information around funding allocation and projected activity it was not possible to develop the local policy further. It was agreed that, in line with NHS England recommendations, the interim policy should remain in place until more commissioning information becomes available. **ACTION: Sara Wilds to share the Oxfordshire CCG pathway criteria.**
7.0	**Paper 16-074 – Evidence Review: Sequential use of biologic drugs for psoriasis**
7.1	There are currently five biologic therapies recommended by NICE for the treatment of psoriasis – adalimumab, etanercept, infliximab, secukinumab and ustekinumab. It was noted that they all act in slightly different ways. With regard to national guidance for psoriasis, each of the biologics has an associated NICE Technology Appraisal Guidance (TAG) which supports their use and an option for treatment. There are also NICE guidelines for the management of psoriasis which recommend changing to an alternative biologic after failure to one, as defined in the TAG for each drug, or after loss of response. For adults in whom there is an inadequate response to a second biological drug the advice is to seek supra-specialist advice from a clinician with expertise in biological therapy. NICE do not make recommendations around the subsequent use of biologics after failure of a second agent. The associated NICE costing report states that for people where second biologic has failed 'best supportive care' may be appropriate and estimates the annual cost of biologic treatment to be circa £11,000. The current British Association of Dermatologists Psoriasis guidelines, dated 2009, do not make recommendations for the use of a third biologic, however updated guidelines are due to be published later this year and it has been confirmed that they will make recommendations around this. The Committee agreed that whilst this will be very useful in considering the use of biologics in this condition, it would not be appropriate to delay the development of a policy in order to await the publication of this guidance.

With regard to the evidence, there are only fairly small, short observational studies and retrospective analyses of registries of longer duration. The evidence indicates that patients who had been on more than two anti-TNF's experienced less improvement compared to those patients who had received no previous anti-TNF therapies. It also showed a lower drug survival with subsequent biologic therapies. One analysis demonstrated that ustekinumab showed a lower discontinuation rate compared to other biologics across 1st, 2nd and 3rd line biological cohorts. However analysis from another registry demonstrated that ustekinumab lost its advantage in patients who had been pre-treated with another biologic.

It was acknowledged that the local IFR data probably does not provide a true reflection of what is happening in practice, as although the number of IFR requests is low, local specialists have confirmed that sequential use of biologics is common practice. There is no cost analysis within NICE for the use of a third or subsequent biologic drug. The costing statement from the Secukinumab TAG estimates the number of patients who are eligible for biologic treatment to be 45 per 100,000 population and the annual cost of treatment for each drug ranges from £9k to £16k per year.

The Committee noted feedback received from Dr Venning, Consultant Dermatologist (specialising in biologics) from the Oxford University Hospital Foundation Trust. Dr Venning made the following points:

- the apparent inferior response to second and subsequent biologic is frequently a reflection that some patients have very severe and difficult disease
- biologics are very different drugs acting on different cytokine targets
- persistence in therapy (drug survival) is a composite measure of multiple factors
- use of all 5 biologics in any particular order to be kept as flexible as possible
- the outcomes are nowhere near as good in real life practice as in published trials and that these patients are right at the end of the therapeutic road, with severe disease where treatment failure is disastrous and has to be managed

The local Specialists in attendance agreed with these points.

Dr Eissi, attending specialist, noted that although national guidelines do not currently address the use of sequential biologics, since they have been published there have been rapid advances in the field of biologics. Long term safety data has been published (such as for ustekinumab), and new classes of biologics have been licensed with more in the pipeline. Each works differently and so even if an anti-TNF fails another with a different action may still be beneficial. When patients have severe psoriasis and have had the usual phototherapy, conventional systemic treatment and have failed to respond or have developed side effects, they are then switched to biologics. There are very little other options other than to either admit patients or use day care service (where available) and treat with fluids, antibiotics, topical treatments until the flare up can be controlled. For life threatening episodes, rapid infusion of infliximab is an option. It was noted that in their clinical experience the attending specialists felt that the majority of patients respond to a first or second biologic. The local specialist reported that within Buckinghamshire Health Care Trust, of the 80 psoriasis patients on biologics at present, 90% are doing well with 67% on their 1st biologic and 23% on a 2nd, only 10% are on a 3rd or 4th biologic. Of these 10% more than half are responding well. Dr Eissi advised that the cost of 'best supportive care' estimated by NICE is an underestimate. The clinical specialist noted that if patients could not access subsequent biologic therapy and were not able to receive systemic drugs, most of their care would be day unit treatment or hospital admission which is very costly. Dr Higgins, attending specialist, noted that Royal Berkshire NHS Foundation Trust has 73 patients on biologics and only 2 are on a 3rd biologic. She confirmed that they rarely need to use 4th line biologics and the numbers would be very small.

7.2	The Committee discussed whether any biologic drug would be considered more preferable than the others. The Committee agreed it would not be appropriate to recommend them in any particular order as it is dependent on patient factors and all are supported by NICE TA Guidance. The Committee agreed to recommend the use of any three sequential biologic therapies for patients. The use of a 4th or subsequent biologic would be subject to IFR approval. **ACTION: Clinical Effectiveness team to draft a policy document and circulate for comment with the meeting minutes. Comments are to be received within the 2 week feedback period following issue.**
8.0	**Paper 16-073 – Evidence Review: Sequential use of biologic therapies for psoriatic arthritis**
8.1	There is no overarching NICE Clinical Guidelines for this topic, however there are a number of NICE TAGs. NICE recommend etanercept, infliximab, adalimumab and golimumab for the treatment of psoriatic arthritis (PsA) if patients haven't responded to at least two standard disease-modifying antirheumatic drugs (DMARDs) or the person have three or more tender or swollen joints. Ustekinumab is recommended where treatment with anti-TNF is contraindicated but would otherwise be considered or the person has had treatment with 1 or more anti-TNF inhibitors. NICE state that the least expensive drug (taking into account drug administration costs, required dose and product price per dose) should be used. NICE does not make any recommendations on the sequential use of biologics in PsA but note that the clinical experts who fed into the NICE decision did highlight that sequential use of anti-TNFs is an established practice within the NHS. British Association of Dermatologists (BAD) guidelines state that if a patient has not responded to an anti-TNF another anti-TNF can be considered. British Society for Rheumatology (BSR) guidelines state that at present, there is not enough systematic evidence to identify if switches between certain drugs show better efficacy than others. Generally there was a lower response to a second and subsequent anti-TNF compared to the first drug used. The Committee considered the evidence for sequential use of biologics in PsA. It was noted that there have been no systematic reviews, randomised controlled trials or UK based cost effectiveness studies. Observational studies provide some evidence of drug survival following second or third biologics, with ustekinumab demonstrating the highest drug survival of all biological agents. Previous exposure to a different biologic agent was not observed to be a predictor for treatment drop-out and the failure of an initial anti-TNF was not considered to preclude the response to another one.
8.2	NICE estimates the number of patients who will stop treatment with their first anti-TNF to be 3.7 per 100,000 population. Cost per patient per annum ranges from £9k to £13k.
8.3	Dr Magliano, attending specialist, advised that it is common practice to switch biologic for patients with psoriatic arthritis who have not responded or who have experienced side-effects and from experience patients do very well on switching. The attending specialist reported that Ustekinumab is considered a good alternative if patients are ulcerated, if there is an adverse effect or there is absolutely no response. She highlighted that it is a small number of patients who require biologic therapies and the patients have very limited choices if biologic treatment has failed. Patients will be physically disabled, they may be unable to work, experience a lot of pain, and they often require high dose steroids which can impair mobility. She stated that biologics have completely revolutionised the outcome for psoriatic arthritis patients and would not support restricted access for patients who require them most.
8.4	The Committee agreed that up to three biologic treatments (including ustekinumab) would be recommended. The use of a 4th or subsequent biologic would be subject to IFR approval. The Committee agreed the flow chart pathway included in NHS Lambeth CCGs policy was useful and should be amended and included within the policy. **ACTION: Clinical Effectiveness team to draft a policy document and circulate for comment with the meeting minutes. Comments are to be received within the 2 week feedback period following issue.**

9.0	**Paper 14-068 – Follow Up: Review of sequential use of anti-vascular endothelial growth factor treatment (anti-VEGF) treatment and steroid implants in ophthalmology**
9.1	This topic was discussed at the last Committee meeting in May 2016 with a consultant ophthalmologist present. The committee had considered the sequential use of biologics in wet Age-related Macular Degeneration (AMD), Retinal Vein Occlusion (RVO) and Diabetic Macular Oedema (DMO). The Committee had asked for a summary of the exit criteria to clarify when biologic treatment in these conditions should be stopped. National Guidance relating to this was summarised. NICE TA155, Ranibizumab and Pegaptanib in AMD, suggests criteria for discontinuation should include persistent deterioration in visual acuity and identification of anatomical changes in the retina that indicate inadequate response to therapy. NICE TA283, Ranibizumab for RVO, states that if there is no improvement in visual acuity over the course of the first 3 injections, continued treatment is not recommended. The Royal College of Ophthalmologists RVO guidelines state that stopping ranibizumab and aflibercept therapy should be considered if after three consecutive monthly treatments, visual acuity has not improved by at least five letters and CMT has not reduced from baseline.
	Attending specialist, Mr Sim, joined the meeting.
9.2	The attending specialist, Mr Sim, advised that in his practice the maximum number of injections given is 6 and that in some patients it is possible to tell after 3 injections that treatment is not going to work. Sometimes a patient's vision is a lot worse and sometimes you have a situation where vision is no better so there is no point in continuing. As far as switching treatment is concerned he felt that aflibercept is longer lasting and more potent than ranibizumab. Patients who have partial response to ranibizumab and don't get a good result after 6 injections are switched to aflibercept. In some patients, frequent injectors require injections on a monthly basis to achieve an effect and by switching to aflibercept only administered every two months reduces the injections required. For aflibercept if after 3 injections there is still no response then the clinician would consider stopping the treatment. The Committee discussed using the NICE recommendation of no improvement within 3 months as a criteria for stopping biologic treatment. The attending specialist agreed that 'persistent' in this case could be defined as the last 3 months.
9.3	The Committee agreed that where treatment with a first biologic fails or is stopped due to adverse drug reaction, a second biologic treatment will be funded in patients with wet AMD, RVO and DMO where all NICE criteria are met. It was agreed that where no improvement in visual and anatomical improvement is seen after 3 months, as defined by NICE and RCO guidelines, treatment should be stopped. **ACTION: Clinical Effectiveness team to draft the policy document with the exit criteria and circulate for comment with the meeting minutes. Comments to be received within the 2 week feedback period following issue.**
10.0	**Paper 16-075 Policy Update: Surgery for painful big toe**
10.1	There is variation in the number of surgical procedures being performed for bunions across Thames Valley CCGs and variation in the levels of activity compared to the national average. The Thames Valley CCG federations and Oxfordshire CCG currently have their own policy statements relating to bunion surgery.
10.2	Hallux valgus is thought to be common with a prevalence of 28.4% in adults older than 40 years. There is a strong genetic association and expert opinion cites footwear as a cause in 34% of cases. Mild symptoms can be managed with patient information, simple analgesia, ice, bunion pads and modification of footwear. Surgery is an option for painful bunions depending on the severity. The most common surgical intervention is osteotomy. The only current available national guidance on surgery for bunions is the Royal College of Surgeons (RCS) Commissioning Guidance: Painful deformed great toe in adults (2013). This sets out the pathway for Primary, Intermediate and Secondary care. No evidence was identified

	regarding referral criteria or thresholds for surgery. Very little evidence compares conservative treatment for bunions with surgical treatment. One systematic review and one experimental study were identified and considered, which evaluated the effectiveness of orthosis in bunion treatment. With regard to activity last year there were 144 prior approvals sought for surgery across Buckinghamshire and Berkshire CCGs. Local activity, according to the RCS, ranges from 2.3 to 31.7 surgical interventions per 100,000 population across the Thames Valley CCGs. The national average is 16. Over the last 3 years the cost of surgery associated with hallux valgus across Thames Valley was just over £4.6m in total. Costs range per intervention from £800 to £6,800.
10.3	Feedback received from Mr Clark, Frimley Health NHS Foundation Trust was fed into discussions and noted. It was also noted that the podiatry lead from Oxford Health NHS Foundation Trust advised that CCGs are charged £109 per custom made sole and an additional charge for assessment and follow up.
10.4	The attending specialist, Mr Mahedevan, advised that patients with mild to moderate deformity would not need early intervention surgery. He highlighted the importance of avoiding high heeled shoes and moving to roomier footwear with soft leather uppers as a key early intervention. The Committee was advised that there is little that can be done conservatively for potentially more severe bunions and toes that are 'stuck' and have lost flexibility. A customised shoe would be required. The attending specialist suggested that criteria for surgery might include: • Severe and inflexible deformity. Mr Mahedevan advised that he felt this is more important than x-ray, which is a criteria included within the Buckinghamshire and Berkshire CCGs current policy. Evidence of radiographic damage was agreed not be a useful criteria for inclusion within the policy. • Transfer pain: If deformity is severe, a transfer lesion can develop, which gives the feeling of walking on a pebble, and the big toe won't go down. Lesser toes become involved and are difficult to manage. It was felt that the policy criteria should be more specific as to which patients should be referred into secondary care. All patients should go through the initial conservative management process. A timeframe of 3 months was agreed to be appropriate. The Committee discussed the use of Orthotics and the attending specialist advised that he did not think they worked particularly well for bunions but they may be an option if a patient is not suitable for surgery. The Committee agreed that the policy should highlight the importance of information and education of the patient regarding footwear and also ensuring the patient understands the outcomes of surgery. Conservative treatment should be tried for at least 3 months. Referral for consideration of surgical treatment is then appropriate where: • a toe is not passively correctable to the neutral position • there is transfer pain to the second metatarsal **ACTION: Clinical Effectiveness team to update the current Oxfordshire policy document to include the criteria above and circulate with the minutes in the usual manner.**
11.	**Any Other Business**
11.1	Patellar resurfacing as part of Total knee replacement: Clinical Effectiveness team have received a request from Buckinghamshire CCGs for a joint Thames Valley patellar resurfacing review and potential policy, to be added to the September agenda. The Committee felt that, as the next version of HRG codes (HRG4+), which changes the pricing structure to diminish the pricing difference for patella resurfacing, is expected to be available for financial year 2017/18, it was not an efficient use of resource to develop a joint policy for this short period of time. Berkshire West CCGs have already adopted a 'not normally funded policy' for patella resurfacing at the HR05Z price. It was noted that the policy as it stands does not provide clinical thresholds to support IFR decision making, however, the Committee agreed to continue with the current arrangements for the moment.

11.2	Aesthetics Policy – criteria for ptosis of the eyelid to be included within the aesthetics policy. **ACTION: Clinical Effectiveness team to add to the work programme.**
11.3	Oxfordshire Trust board meeting is on the same day as the TVPC meeting. The Committee agreed to investigate whether the TVPC meeting could be moved to an alternative Wednesday on the understanding that attendance would be assured. **ACTION: Clinical Effectiveness team to investigate alternative suitable dates.**
12.	The next meeting will be **Wednesday 28th September 2016, held in Conference Room A, Jubilee House, Oxford, OX4 2LH**
13.	**Meeting Close**
	The Chair thanked everyone for their contributions to the discussions and closed the meeting.