

Thames Valley Priorities Committee

Minutes of the meeting held Wednesday 22nd May 2019

Room G29/G30, 57-59 Bath Road, Reading RG30 2BA

Alan Penn	Lay Member Chair	Thames Valley Priorities Committee
Linda Collins	Clinical Effectiveness Manager (CCG)	Oxfordshire CCG
Lindy Gilham	Assistant IFR Manager	SCW CSU
Edward Haxton	Deputy Finance Director	Berkshire West CCG
Dr Megan John	GP, East Berkshire CCG Lead	East Berkshire CCG
Prof. Chris Newdick	Professor of Health Law	University of Reading
David Pollock	Clinical Integration Pharmacist	Berkshire West CCG
Dr Raju Reddy	Secondary Care Consultant	Berkshire West CCG
Sarah Robson	Head of IFR	SCW CSU
Amaka Scott	Commissioning Interfacing Pharmacist	Berkshire West CCG
Dr Karen West	Clinical Director Integration	Buckinghamshire CCG
Dr Raju Reddy	Secondary Care Consultant	Berkshire West CCG
Amaka Scott	Commissioning Interfacing Pharmacist	Berkshire West CCG
Dr Karen West	Clinical Director Integration	Buckinghamshire CCG

In Attendance:

Tiina Korhonen	Clinical Effectiveness Lead	SCW
Kathryn Markey	Clinical Effectiveness Manager	SCW
Katie Newens	Clinical Effectiveness Researcher	SCW

Topic Specialists in Attendance for Agenda Items:

Item 7 – Pathway for Crohn’s treatment with biologics		
Dr Oliver Brain	Consultant Paediatrician, Paediatric Endocrine Lead,	Wexham Park / Frimley Health NHS Foundation Trust
Item 8 – Evidence Reviews: Breast reconstruction surgery post breast cancer; Risk reduction surgery for breast cancer & Policy Update: Biological mesh for reconstruction		
Nicky Dunn	Consultant Oncoplastic Breast Surgeon and Clinical Lead for Breast Surgery	Royal Berkshire Hospital
Item 9 – Evidence Review: Sequential use of biologic drugs for ankylosing spondylitis and axial spondyloarthritis		
Prof. Paul Bowness	Consultant Rheumatologist	Oxford University Hospital
Antoni Chan	Consultant Rheumatologist	Royal Berkshire NHS Foundation Trust

Apologies:

Jane Butterworth	Medical Director	Oxford Health NHS Trust
Catriona Khetyar	Head of Medicines Optimisation	East Berkshire CCG
Ravi Lukha	Public Health Specialist Registrar	Public Health Services for Berkshire
Robert Majilton	Deputy Chief Officer	Buckinghamshire CCG
Dr Matt Mayer		Berkshire, Buckinghamshire & Oxford LMC
Dr Jacky Payne	GP	Berkshire West CCG
Rachel Finch	Clinical Effectiveness Administrator	SCW
Catriona Khetyar	Head of Medicines Optimisation	East Berkshire CCG
Ravi Lukha	Public Health Specialist Registrar	Public Health Services for Berkshire

1.	Welcome & Introductions
1.1	The Chair opened the meeting and welcomed the members of the Committee.
2.	Apologies for Absence
2.1	Apologies recorded as above. This meeting was not quorate. Clinical Effectiveness team to circulate minutes detailing any policy recommendations made by the Committee to absent member for agreement post hoc as per ToR.
3.0	Declarations of Interest
3.1	Nothing declared.
4.	Draft Minutes of the Priorities Committee meeting held 27th March 2019 - Confirm Accuracy
4.1	The draft minutes were accepted as a true record of the meeting.
5.	Draft Minutes of the Priorities Committee meetings – Matters Arising
5.1	Minutes of the Priorities Committee held in July 2018 – Action 6.6.2 - Paper 18-006 – Evidence Review: Sequential use and dose escalation of biologics in Crohn’s disease Attending specialist clinicians agreed to develop a policy and pathway for the sequential use of biologics in Crohn’s disease with their colleagues from Oxford, Reading, Buckinghamshire and Frimley. May 2019 Update: Refer to item 7 below.
5.2	Minutes of the Priorities Committee held in January 2019 – Action 11.1 - Paper 18-032 – NHSE Evidence based interventions (EBI) – Update The Clinical Effectiveness team to schedule policies for chalazia and tonsillectomy for early review and adoption. March 2019 Update: Proposed for discussion at 22 nd May 2019 Committee meeting. May 2019 Update: Scheduled for discussion at 24th July 2019 Committee meeting.
5.3	Minutes of the Priorities Committee held in January 2019 – Action 13.1 – Any Other Business – Public Health representation at Case Review Committee/equity audits A question was put to the Committee regarding what equity audits have been carried out about the impacts of our policy recommendations, and whether socio economic status and ethnicity are audited. March 2019 Update: ACTION: CCGs to discuss and work with the Head of IFR as to the best method of extracting a report(s) by GP practice over at least two financial years for socio economic status and ethnicity analysis. Review report to be discussed at the Committee Workshop topic scoring event to be held in November 2019. Action with CCGs and IFR team.
5.4	Minutes of the Priorities Committee held in March 2019 – Action 6.6 - Paper 18-034 – Evidence Review: Continuous glucose monitoring; paediatric The Clinical Effectiveness team to seek attending specialist input regarding the ACDC guideline CGM withdrawal criteria to clarify whether all or some of the withdrawal criterion should to be met. ACTION Complete

5.4 Cont..	The Clinical Effectiveness team to draft a policy recommendation: Continuous glucose monitoring (CGM) – paediatrics and circulate for comment. Comments to be received within the 2 week feedback period following issue. ACTION Complete
5.5	Minutes of the Priorities Committee held in March 2019 – Action 7.5 - Paper 18-035 – Evidence Review: Management of ear wax The Clinical Effectiveness team to draft a policy recommendation: Management of ear wax and circulate for comment. Comments to be received within the 2 week feedback period following issue. ACTION Complete
5.6	Minutes of the Priorities Committee held in March 2019 – Action 8.5 - Paper 18-036 – Evidence Review: Lignocaine infusions for chronic pain The Clinical Effectiveness team to draft a policy recommendation: Lidocaine infusions for chronic pain and circulate for comment. Comments to be received within the 2 week feedback period following issue. ACTION Complete
5.7	Minutes of the Priorities Committee held in March 2019 – Action 9.1 - Paper 18-037 – Review: Ethical Framework ‘Exceptionality’ The Clinical Effectiveness team to update the Thames Valley Priorities Committee Ethical Framework paragraph 8 ‘Exceptional Need’ and circulate for comment. Comments to be received within the 2 week feedback period following issue. ACTION Complete
5.8	Minutes of the Priorities Committee held in March 2019 – Action 10.1 - Paper 18-038 – Current Policy Updates The Clinical Effectiveness team to update the policies identified in Paper 18-038 as requiring ‘minor change’ and circulate for comment. Comments to be received within the 2 week feedback period following issue. ACTION Complete
5.9	Minutes of the Priorities Committee held in March 2019 – Action 12.1 - Paper 18-041 & 18-041a – Flash Glucose Monitoring System The Committee acknowledges that it has to agree the national policy set out by NHS England. The TV heads of Medicines Optimisation have been working on this and drafting documents on behalf of Frimley and are happy to share with the Committee and across the TV. It was also agreed that whilst we use the national policy we expect to continue to use of the Thames Valley Patient agreement. East Berkshire agreed to provide a copy of updated documents including updated policy, patient agreement and frequently asked questions. ACTION Complete The Clinical Effectiveness team to update the TVPC 73 Flash Glucose Monitoring System - FGS (Freestyle Libre®) policy and the associated papers and circulate for comment. Comments to be received within the 2 week feedback period following issue. ACTION Complete
6.	Paper 19-001 – Policy Update: TVPC13 Ketone Testing
6.1	This policy is for adults with Type 1 diabetes and a very small number of high risk patients with Type 2 diabetes. The policy was discussed at the TVPC meeting in January 2019, where minor changes were recommended. The feedback received from CCGs and clinicians requires further consideration by the Committee. The current policy states who should be prescribed the strips, when to test for ketones and how “sick days” should be managed. The Committee are asked to consider the following suggestions which were received through consultee feedback: <ul style="list-style-type: none"> • Whether to use the “sick day” rules published by Dose Adjustment for Normal Eating (DAFNE) as some providers are now using this guidance • Add the tariff for additional strips e.g. GlucoRx HCT ketone strips • Widen the prescription of ketone strips to all patients with Type I diabetes, and consider other groups such as children. Alternatively the policy could be withdrawn with a recommendation for medicines optimisation teams to develop CCG specific policies with providers to reflect variations in local diabetes education programmes.

6.2	<p>The Committee discussed the potential cost implications of widening the prescription of the ketone strips to all patients with Type 1 diabetes, however current practice was unclear. Due to the differing guidelines used by providers across Thames Valley, the Committee decided to recommend withdrawal of the policy.</p> <p>ACTION: The Clinical Effectiveness team to draft withdrawal recommendation paperwork for policy TVPC13: Ketone testing and issue to CCG Governing Bodies for endorsement.</p>
7.	<p>Paper 19-002 – Pathway for the management of Crohn’s disease with biologics</p>
7.1	<p>It was agreed at the TVPC meeting in July 2018 that a Thames Valley wide pathway for the use of biologic drugs in the management of Crohn’s disease would be developed with clinicians from Thames Valley providers.</p>
7.2	<p>The specialist in attendance raised the following points:</p> <p>The pathway suggests that most patients with Crohn’s disease will receive anti-TNF drugs first. Due to the development of biosimilars, anti-TNFs are likely to be the cheapest. They are also the best drugs for people with perianal disease as there is still no clear evidence that other biologics work for perianal Crohn’s disease.</p> <p>The pathway maximises the use of anti-TNFs by the use of immunomodulators and measurement of drug levels and states they should be first line in most cases but not all. There are two other options: the anti-IL-12/23 or vedolizumab.</p> <p>There are many patients for whom anti-TNFs are not the most appropriate option. Pathways become very quickly out of date. Since this pathway has been written there has been a big study published and more evidence about anti-TNF use. More is now known about which patients are likely to lose response to anti-TNFs. These patients are likely to be: obese; smoke; unable to tolerate an immunomodulatory; carry a specific geno type for which the Oxford clinic have started to carry out genetic tests.</p> <p>Using anti-TNFs first line would be the wrong thing to do as almost without doubt a patient would lose response in that first year because of anti-drug antibodies. Evidence suggests at the moment the problem of anti-drug antibody formation is not seen with ustekinumab and vedolizumab and a concomitant immunomodulator is not needed therefore these drugs might be the best first choice. This pathway is therefore likely to be suitable for most patients but not all.</p> <p>The pathway has been circulated to Thames Valley provider colleagues.</p> <p>It is important that it is recognised that this pathway is guidance rather than a mandatory process that every patient must follow.</p>
7.3	<p>The committee felt that it is reasonable to suggest that an anti-TNF is first choice unless the patient is unable to tolerate an anti-TNF; an anti-TNF is contraindicated or a patient is not a good candidate for an anti TNF and this can be defined.</p> <p>With regards to failing 2 or 3 biologics, the specialist advised that for both ulcerative colitis and Crohn’s Disease there is a lower response rate to each subsequent biologic but it does not mean there will be zero response and response will depend on each individual case. For a lifelong disease that can evolve and change, that is not surgically removable and where the immune system evolves and changes), it is right to have the option of other biologics. The Committee discussed the use of sequential biologics in the presence of the specialist.</p> <p>If a patient is no longer able to take a biologic, options include participation in clinical trials and surgery.</p>

<p>7.3 Cont..</p>	<p>The Committee heard that in extreme cases, people end up with short bowel and on total parenteral nutrition (TPN) which is very expensive. A patient may also require a stem cell transplant which might put them into remission for a few years before the disease then flares again.</p> <p>The Committee discussed that funding for a 4th or subsequent biologic would be appropriate when the patient would otherwise have to have an alternative expensive treatment. The Committee discussed the importance of reviewing the policy in light of new evidence.</p> <p>ACTION: The Clinical Effectiveness team to draft a policy recommendation: Crohn’s disease - pathway for treatment with biologics and circulate for comment. Comments to be received within the 2 week feedback period following issue.</p>
<p>8.</p>	<p>Paper 19-003 Evidence Review: Breast reconstructive surgery post breast cancer</p>
<p>8.1</p>	<p>The Thames Valley CCGs have requested a review of reconstructive surgery post breast cancer. Survival rates from breast cancer have improved over recent decades. This has inevitably led to an increasing number in requests for additional procedures over time to the planned index and reconstruction surgery. The issue of the number of reconstructive procedures post cancer and the time line of continued reconstructive support has been discussed by many CCGs; nationally and regionally some CCG’s have introduced policies to set out time limits or the number of reconstructive procedures the CCGs are prepared to fund post index surgery. The patient group in question is women who are seeking further adjustments a number of years post reconstruction completion which may be considered to come under the cosmetic surgery policy.</p> <p>The review took account of national guidance and local data on post breast cancer reconstructive surgery including; surgery on the affected breast, surgery on the contralateral side and lipofilling. The mainstay of breast cancer treatment is surgery, either mastectomy or breast conserving surgery. The burden of the number of reoperations rests on the women who have mastectomy. Reconstructive surgery post mastectomy can be immediate or delayed.</p>
<p>8.2</p>	<p>Currently there is no national guidance or evidence to determine which breast reconstruction technique delivers the best outcome for any individual patient or the most cost effective technique. Similarly it is not known what the average number of procedures required to optimise a reconstruction. The Association of Breast Surgery (ABS) British Association of Plastic, Reconstructive & Aesthetic Surgeons (BAPRAS) Breast Cancer Now (BCN) (2018) Guidance for the Commissioning of Oncoplastic Breast Surgery notes that due to the complexity of the cancer and patient related factors it is thought that post index surgery and planned surgery would be a programme of operations. The initial procedure including the cancer removal followed by 2 or 3 second stage ‘adjustment’ surgeries is quite normal over 18-24 months to optimise appearance and symmetry.</p> <p>Across Thames Valley CCGs there are approximately 2,000 women per year undergoing index surgery. Majority of women have breast conserving surgery, mastectomy being carried out in 29% of women with most women opting for delayed reconstruction. Local data on post index surgery revision indicates that balancing surgery as a revision is carried out in small numbers of women across TV; <10 in 2015-16, 11 in 2016-17 and 14 in 2017-18. Lipofilling is used in a small number of operations.</p>

<p>8.3</p>	<p>The specialist in attendance noted that we are talking about cancer patients at a time of increased stress and emotional and psychological upheaval. For some women immediate reconstruction is self-evident and for some the cancer treatment is a priority and thoughts on reconstruction may come later. Locally, reconstruction is offered to everyone but the default is to try to do breast conserving surgery if possible. The national breast reconstruction audit has shown that physiological outcomes are much better for breast conservation compared to mastectomy and outcomes were better in women who had had reconstruction compared to those who hadn't. The specialist noted that the surgeons do set the patient expectations in terms of what surgery can achieve to avoid additional request for adjustments. The patients are also told that there will be changes over time which is natural. On average revision of surgery may be necessary over 10 year period, but it is highly variable, depending on type of reconstruction and the need for radiotherapy. Overall, in the first year you may have a number of operations. After that for people who have had autologous reconstruction with no implants generally there are no requirements for maintenance. With implant based reconstruction there's potential for the need of maintenance and that can come at any time period. The clinician noted that this is going to come up more as more of these patients are living longer.</p> <p>In reference to balancing surgery on the unaffected breast the specialist agreed that for small asymmetry balancing is not necessary. However, for a significant asymmetry it would be inappropriate not to offer surgery. Yet, it would be difficult to set limits on the volume, as a threshold, as it may only become apparent at the time of surgery and will depend on the later response to radiotherapy. The clinicians would support the option 1 in the review paper; of no specific policy on the reconstructive surgery post breast cancer, based on the acknowledgement that breast reconstruction is a process rather than a single event and that additional adjustment procedures post mastectomy are likely to be required to optimise cancer and aesthetic outcomes and support high quality survivorship.</p>
<p>8.4</p>	<p>The Committee considered the local data and the clinical feedback. The need for policy was questioned as the Committee was reassured that the surgeons are giving messages that they are not doing anything that is not necessary. Yet, it was agreed that without having a statement there is potential for continued and increasing demand for surgery to produce symmetry or improved cosmetic appearance post completion of the reconstruction several years later. The Committee agreed that setting a time line would be arbitrary but post completion of initial reconstruction 5 years would represent discharge from the cancer pathway and affect only a small number of patients. Committee agreed that it was not appropriate to set limit on the number or type of procedures carried out as part of the reconstructive surgery.</p>
<p>8.5</p>	<p>Following discussion the Committee agreed the Clinical Effectiveness team to draft a policy recommendation for post breast cancer reconstructive surgery to include the following:</p> <ul style="list-style-type: none"> • Any surgery post 5 years after the completion of the initial reconstructive surgery will not be funded • Include reference to TVPC16 Aesthetic treatment for adults and children policy <p>The Committee considered whether the recommended policy represents a change in service provision, however, it was agreed that the recommendation does not impact on the provision of services for the planned reconstructive surgery, whilst the patient is in the cancer pathway.</p>

8.5 Cont..	ACTION: The Clinical Effectiveness team to draft a policy for post breast cancer reconstructive surgery and circulate for comment. Comments to be received within the 2 week period feedback period following issue.
9.	Paper 19-004 Evidence Review: Risk reducing surgery for breast cancer
9.1	<p>The Thames Valley CCGs have requested a review in view of adding a guidance note on prophylactic mastectomy to the current TVPC16 ‘Aesthetic treatment for adults and children’ policy, due to the numbers of Individual Funding Requests (IFRs) received by the CCG teams. The aim of this review is to consider the national guidance and local data for risk reducing breast surgery. The review is based on the current NICE clinical guideline CG164 ‘Familial breast cancer.’</p> <p>Familial breast cancer typically appears in people with high numbers of family members affected by breast cancer, ovarian or a related cancer. About 5% of all breast cancers arise from a gene mutation, the most common inherited altered genes that increase the risk of breast cancer developing are BReast CAncer1 (BRCA1), BReast CAncer2 (BRCA2) and more rare TP53 (tumor protein p53). Based on UK incidence data, a woman aged 20 who has no affected relatives has a 7.8% probability of developing breast cancer by the age of 80; with 1 affected relative this probability rises to 13.3% and with 2 affected relatives to 21.1%. Breast screening and risk-reducing treatments are offered to women in increased risk groups. Bilateral mastectomy may be used as a risk-reducing strategy in women at high risk of breast cancer due to their family history.</p> <p>NICE CG states that: Bilateral risk-reducing mastectomy is appropriate only for a small proportion of women who are from high-risk families and should be managed by a multidisciplinary team. NICE CG also notes that women considering bilateral risk-reducing mastectomy should have genetic counselling in a specialist cancer genetic clinic before a decision is made. NICE notes that for people who are at increased risk, genetic testing and risk-reducing surgery would allow them to make decisions on how to reduce their cancer risk and could help avoid costly treatments. Savings would be difficult to quantify because they depend on a number of variables, including the stage of the cancer and the type of treatment needed. Local data indicates that across TV there has been an average 30 women annually over the last three years who have had bilateral mastectomy with no cancer diagnosis.</p>
9.2	<p>The attending clinician noted that unfortunately currently the patients are often diagnosed with cancer and then found to be a gene carrier. If detected, only high risk patients are offered risk reducing surgery. For women who have had a breast cancer diagnosis a small proportion will request risk reducing surgery on the other breast for anxiety and cancer phobia. The clinical approach is that if they are not high risk we will discuss it with them, review their risk outcome from their index cancer, go through our multi-disciplinary team and ask the patient to see clinical psychology, sometimes we seek a second opinion; we very much try not offer surgery to women who are non-high risk.</p>
9.3	<p>The Committee agreed that a guidance note should be added to the current TVPC16 ‘Aesthetic treatment for adults and children’ policy to clarify that risk reducing surgery is funded according to the NICE CG164 recommendations; ‘for women in the high risk category for breast cancer who have had genetic counselling or who’s family history has been verified where no mutation has been identified. Where no family history verification is possible, agreement by a multidisciplinary team should be sought before proceeding with bilateral risk-reducing mastectomy’.</p> <p>ACTION: The Clinical Effectiveness team to draft guidance note to TVPC16 ‘Aesthetic treatment for adults and children’ policy for risk reduction surgery for breast cancer and circulate for comment. Comments to be received within the 2 week feedback period following issue.</p>

10.	Paper 19-005 Policy Update: TVPC14 Biological mesh for reconstruction
10.1	<p>This policy was developed four years ago and covers where biological mesh can be considered as an option for breast reconstruction. One of the potential advantages of using mesh is that it can be used for immediate reconstruction with a single procedure rather than the traditional two stage approach. At that time, it was advised that anticipation of radiotherapy treatment should be a contraindication.</p> <p>The evidence review identified Joint Guidelines from the Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons which were based on low level evidence, and systematic reviews which were limited by the low level of evidence available. A randomised controlled trial found that the single stage technique with mesh led to poorer outcomes than the two stage technique which did not use mesh. A recent national audit paper has also been published which raised concerns of high levels of implant loss, readmission, reoperation, infection with immediate implant based breast reconstruction. However, none of the evidence identified was able to ascertain which reconstruction method is optimal for women requiring future radiotherapy.</p>
10.2	<p>Feedback received from Oxford University Hospital asks the committee to reconsider the requirements for anticipation of radiotherapy from a clinical perspective and also from a practical perspective (may be unclear at the time of surgery whether the patient is going to require radiotherapy).</p> <p>The attending clinician noted that the need for radiotherapy is generally anticipated as the main determinants are the size of the tumour and whether the lymph nodes are involved; oncology practice varies slightly, but generally if the tumour is over 5cm and there is one lymph node involved then the oncologist will give radiotherapy after mastectomy. As techniques are changing in regards to where the implant is situated, there is likely to be changing opinion about the significance of radiotherapy as if the implant is on top of the muscle and not confined by anything, there is a theory that radiotherapy may not have such a significant impact. It's an area of big debate in breast reconstruction.</p>
10.3	<p>Due to the differing clinical views surrounding the use of mesh for women undergoing radiotherapy following mastectomy, the Committee decided that this section of the policy should be reworded to indicate that the potential risks should be clearly communicated to patients undergoing this procedure.</p> <p>Following discussion the Committee agreed to recommend to update TVPC14 Biological mesh for reconstruction as follows:</p> <ul style="list-style-type: none"> • Remove the requirement for entering patients into the iBRA national breast reconstruction audit and include an alternative viable option if available • Remove the anticipation of radiotherapy as a contraindication to the use of mesh but include wording on communicating the potential risks to patients who are considering the procedure <p>ACTION: The Clinical Effectiveness team to draft an update to TVPC14 Biological mesh policy and circulate for comment. Comments to be received within the 2 week feedback period following issue.</p>
11.	Paper 19-006 Evidence Review: Sequential use of biologic drugs for ankylosing spondylitis and axial spondyloarthritis
11.1	<p>Thames Valley Priorities Committee requested a review of the sequential use of biologics for axial spondyloarthritis. There is currently no Thames Valley wide commissioning policy for the use of biologic drugs in axial spondyloarthritis. Buckinghamshire CCG and Buckinghamshire Healthcare Trust hold a pathway for the use of biologic drugs for ankylosing spondylitis and non-</p>

<p>11.1 Cont..</p>	<p>radiographic axial spondyloarthritis in adults. Spondyloarthritis encompasses a group of inflammatory conditions with some shared features, including extra-articular manifestations. Both peripheral and axial joints can be affected. Axial spondyloarthritis is an umbrella term and includes ankylosing spondylitis and non-radiographic axial spondyloarthritis which primarily affect the spine, in particular the sacroiliac joint. Changes to the sacroiliac joints or the spine can be seen on x-ray in ankylosing spondylitis. X-ray changes are not present but inflammation is visible on MRI in non-radiographic axial spondyloarthritis.</p>
<p>11.2</p>	<p>NICE clinical guidance for spondyloarthritis in over 16s states that if a patient cannot tolerate the first anti-TNF or the disease has not responded, another TNF alpha inhibitor is recommended. For axial spondyloarthritis there are NICE technology appraisals (TAGS) for the TNF alpha inhibitors: adalimumab, certolizumab pegol, etanercept, golimumab and infliximab. All are recommended after the failure of NSAIDs. There is also a NICE TAG for secukinumab. Secukinumab targets interleukin 17A and is an option in patients who have not responded to NSAIDs or TNF alpha inhibitors.</p> <p>For non-radiographic axial spondyloarthritis, the associated NICE TAG states that the TNF alpha inhibitors, adalimumab, certolizumab pegol, etanercept and golimumab are recommended after the failure of NSAIDs.</p> <p>A NICE TAG for ixekizumab for treating axial spondyloarthritis and a NICE TAG for secukinumab for treating non-radiographic axial spondyloarthritis are expected to be published. Publication dates are currently unknown.</p>
<p>11.3</p>	<p>There is very little evidence available that actually addresses sequential use of biologic drugs. There was one robust systematic review (2016) which drew on results from Registry data and concluded that sequential treatment with anti-TNFs can be worthwhile for patients with ankylosing spondylitis.</p> <p>Drug survival and response rates may diminish with 2nd and 3rd anti-TNFs. The Committee was provided with a summary of biologics, mode of action, marketing authorisations, dose and cost, for axial spondyloarthritis.</p> <p>Feedback received from a specialist clinician in Buckinghamshire (not present) indicated that there may be clinical benefit and financial benefit from using secukinumab as a first line option alongside TNF inhibitors, as a treatment option for patients on a case by case basis. Secukinumab works more quickly than TNF inhibitors and maybe an option in some patients.</p> <p>Both attending specialist clinicians presented the pathways from their respective Trusts.</p>
<p>11.4</p>	<p>The specialist in attendance raised the following points: This is a very debilitating disease affecting young people in their 20s. TNF inhibitors were a fantastic step change in being able to treat these patients. Registry data show that patients remain on the drugs because they work. Registry data do show that the use of a 2nd and 3rd TNF are effective (less effective) and probably for economic reasons no one has conducted a trial. Secondary failure can occur due to the development of antibodies against the drug and this may be an argument for switching between TNF alpha inhibitors. For patients who are considering becoming pregnant, certolizumab is an option as it does not cross the placenta and is therefore considered to be safe in pregnancy. It is important to have the option of the anti iL17s as a completely new method of action so patients who have previously received TNF inhibitors should have the option of going onto secukinumab or ixekizumab if this becomes NICE approved.</p>

<p>11.4 Cont..</p>	<p>This group of conditions have a lot of extra particular features as well, not only does it affect the spine, there is evidence that in suppressing the disease does help the other manifestations of the condition as well which have been outlined in the pathway for decision making and choice of treatment.</p> <p>Both specialists advised that if the patient has no features to suggest choosing an anti-IL17, the cheapest available biosimilar drug (currently Imraldi®) is used.</p>
<p>11.5</p>	<p>Some patients using the biosimilar with citrate have been switched back to the originator biologic.</p> <p>A non-responding patient would be given at least 2 anti-TNFs, with different mechanisms. For a patient who is under 30, not responded and they have not previously had an anti-IL17 before then an anti-IL17 would be tried. An option of 3 biologics is good in patients who do not respond rather than patients experiencing adverse events. For patients who suffer an adverse event, a switch to a different anti TNF would be an option.</p> <p>The Committee discussed the pathways from the Royal Berkshire Hospital (RBH) and the Oxford University Hospitals (OUH). It appears that both pathways are very similar. It was noted that Buckinghamshire Healthcare Trust plans to update its pathway. The Committee confirmed the recommendation of the RBH pathway across the Thames Valley. It was noted that no feedback had been received from Frimley Health Foundation Trust. It was agreed to correspond with both Buckinghamshire Healthcare Trust and Frimley Health Foundation Trust to advise on the outcomes of discussions.</p> <p>ACTION: The Clinical Effectiveness team to contact the specialist clinicians to clarify:</p> <ul style="list-style-type: none"> • the pathway with regard to pregnancy • an adverse drug reaction or injection site reaction where the patient has responded to the first anti-TNF <p>ACTION: The Clinical Effectiveness team to draft a policy recommendation for the sequential use of biologic drugs for ankylosing spondylitis and axial spondyloarthritis and circulate for comment. Comments to be received within the 2 week feedback period following issue.</p>
<p>12.</p>	<p>Any Other Business</p>
<p>12.1</p>	<p>Hearing aid policy</p>
<p>12.1</p>	<p>OCCG raised a request to clarify the title of a recent policy recommendation TVPC86 Hearing aids for adults. This is due to noting that the policy does not include treatments for ‘tinnitus. The Committee agreed to the suggestion that the policy is renamed ‘Hearing aid for hearing loss’.</p> <p>ACTION: The Clinical Effectiveness team to amend the title of policy TVPC86 Hearing aids for adults to ‘Hearing aids for hearing loss in adults’.</p>
<p>12.2</p>	<p>Psoriasis update: TVPC 44 Sequential use of a third or subsequent biologic therapy for psoriasis</p>
<p>12.2</p>	<p>The Committee heard that Oxfordshire CCG has made local amendments to TVPC44. Oxford University Hospitals Foundation Trust is a supra specialist centre dermatology. The Centre believes that they manage patients who are much more likely to require their 3rd biologic. The associated NICE guidance advises that supra specialist advice from a clinician with expertise in biological drugs should be sought before the use of a 3rd biologic drug. The Centre has requested the use of 4 or 5 biologics. Oxfordshire CCG did not agree to the use of 5 biologics. Oxfordshire CCG has reached a consensus with the OUH that actually whilst for most people 3 is</p>

<p>12.2 Cont.</p>	<p>reasonable. A lot of these patients have only been on anti-TNFs because these were all that was available and therefore some patients have not had the opportunity to try a biologic with a different mode of action. The current wording of the policy states that ‘sequential use of a 4th and subsequent use of a biologic therapy is not normally funded’. Oxfordshire CCG has included ‘except for a change to a 4th agent with a mode of action which has not been used before, a change to a 4th drug with a mode of action which has been used before will not normally be funded.’ The policy also states that a patient may switch back to the originator drug if an adverse drug reaction is experienced. This will not be viewed as a switch to a different biologic. In addition a switch from the first line drug due to a documented local injection site reaction, to a 2nd biologic will not be viewed as a switch to an alternative biologic drug. Oxfordshire CCG agreed that dose escalation of adalimumab in line with the British Association of Dermatologists (BAD) guideline will be funded. This policy will be fully reviewed when new guidance and evidence becomes available. In the meantime the Committee agreed to recommend amendment to the policy as Oxfordshire CCG has done, apart from the reference to dose escalation.</p> <p>12.2 ACTION: The Clinical Effectiveness team to draft an update to TVPC 44 Sequential use of a third or subsequent biologic therapy for psoriasis and circulate for comment. Comments to be received within the 2 week feedback period following issue.</p> <p>As general point the Committee discussed the issue of ‘conflict of interest’ that specialist may hold and how this may be addressed in future for topics discussed. The Committee agreed that this should be addressed as part of the review feedback process, without making an overly complex issue.</p> <p>12.2.1 ACTION: The Clinical Effectiveness team to explore the available conflict of interest declarations and add to the standard clinical evidence review and feedback process.</p>
<p>12.3</p>	<p>TVPC Annual Report</p>
	<p>The Committee was asked to review the Annual Report and feedback any comments to the Clinical Effectiveness team.</p>
<p>12.4</p>	<p>TVPC 2019-20 Work Programme</p>
	<p>An updated copy of the TVPC 2019-20 work programme was provided to the Committee for information.</p>
<p>13.</p>	<p>Next meeting</p>
	<p>The next meeting will be Wednesday 24th July 2019, to be held in Meeting Room GU29/30 Bath Road, Reading RG30 2BA</p>
<p>14.</p>	<p>Meeting Close</p>
	<p>The Chair thanked everyone for their contributions to the discussions and closed the meeting.</p>