

## JOINT FORMULARY COMMITTEE (JFC) – MINUTES

Minutes from the meeting held on 20 May 2019

LG01, 222 Euston Road, London, NW1 2DA

|                       |                  |   |                        |
|-----------------------|------------------|---|------------------------|
| <b>Present:</b>       | Dr R Sofat       | UCLH, DTC Chair (NCL JFC Vice Chair)                | <b>(chair)</b>         |
|                       | Dr R MacAllister | NCL JFC Chair                                       | <b>(via telephone)</b> |
|                       | Dr R Woolfson    | RFL, DTC Chair                                      |                        |
|                       | Dr M Kelsey      | WH, DTC Chair                                       |                        |
|                       | Dr A Stuart      | Camden CCG, GP Clinical Lead Medicines Management   |                        |
|                       | Dr R Urquhart    | UCLH, Chief Pharmacist                              |                        |
|                       | Mr P Gouldstone  | Enfield CCG, Head of Medicines Management           |                        |
|                       | Mr A Dutt        | Islington CCG, Head of Medicines Management         |                        |
|                       | Dr S Ishaq       | WH, Consultant Anaesthetist                         |                        |
|                       | Dr K Tasopoulos  | NMUH, DTC Chair                                     |                        |
|                       | Mr S Richardson  | WH, Chief Pharmacist                                |                        |
|                       | Ms P Taylor      | Haringey CCG, Head of Medicines Management          |                        |
|                       | Dr A Sell        | RNOH, DTC Chair                                     |                        |
|                       | Ms W Spicer      | RFL, Chief Pharmacist                               |                        |
|                       | Ms K Delargy     | BEH, Deputy Chief Pharmacist                        |                        |
|                       | Ms L Reeves      | C&I, Chief Pharmacist                               |                        |
|                       | Mr C Daff        | Barnet CCG, Head of Medicines Management            |                        |
|                       | Mr T Dean        | Patient Partner                                     |                        |
| <b>In attendance:</b> | Mr A Barron      | NCL MEP, Lead Pharmacist                            |                        |
|                       | Ms M Kassam      | NCL JFC, Support Pharmacist                         |                        |
|                       | Mr G Grewal      | NCL JFC, Support Pharmacist                         |                        |
|                       | Ms I Samuel      | RFL, Formulary Pharmacist                           |                        |
|                       | Dr P Bodalia     | UCLH, Principal Pharmacist                          |                        |
|                       | Ms S Sanghvi     | UCLH, Formulary Pharmacist                          |                        |
|                       | Mr F Master      | RFL, Formulary Pharmacist                           |                        |
|                       | Dr M Thomas      | ULCH, Consultant haematologist                      |                        |
|                       | Ms C Gates       | UCLH, Clinical Pharmacist                           |                        |
|                       | Dr M George      | UCLH, SpR clinical pharmacologist                   |                        |
| <b>Apologies:</b>     | Ms K Davies      | NEL CSU, Deputy Director Medicines Management       |                        |
|                       | Prof D Hughes    | RFL, Consultant Haematologist                       |                        |
|                       | Ms A Fakoya      | NEL CSU, Senior Prescribing Advisor                 |                        |
|                       | Ms R Clark       | Camden CCG, Head of Medicines Management            |                        |
|                       | Prof L Smeeth    | NCL JFC Vice-Chair                                  |                        |
|                       | Dr M Dhavale     | Enfield CCG, GP Clinical Lead Medicines Management  |                        |
|                       | Mr G Kotey       | NMUH, Chief Pharmacist                              |                        |
|                       | Dr A Bansal      | Barnet CCG, GP Clinical Lead Medicines Management   |                        |
|                       | Prof A Tufail    | MEH, DTC Chair                                      |                        |
|                       | Mr A Shah        | RNOH, Chief Pharmacist                              |                        |
|                       | Dr T Rashid      | NHS Haringey, GP Clinical Lead Medicines Management |                        |
|                       | Mr S Tomlin      | GOSH, Chief Pharmacist                              |                        |
|                       | Dr S Yardley     | CNWL, Consultant in palliative medicine             |                        |
|                       | Mr S Semple      | MEH, Chief Pharmacist                               |                        |

**2. Meeting observers**

Nil

**3. Minutes of the last meeting**

The minutes were accepted as an accurate reflection of the meeting

**4. Matters arising****4.1 Removal of dulaglutide for Type 2 diabetes from the NCL Joint Formulary**

In April 2019 the Committee added semaglutide and removed dulaglutide from the NCL Joint Formulary. The decision was based on both being once-weekly injections at similar cost, however semaglutide was noted as being superior in terms of HbA1c reduction and weight reduction. Dulaglutide was therefore not considered cost-effective compared to semaglutide.

The Committee heard an appeal from Dr Cohen (RFL) against the decision to remove dulaglutide based on perceived benefit of the dulaglutide auto-injector pen compared to the semaglutide pen. The Committee agreed that trade-off between drug inferiority and ease of administration only favoured dulaglutide in a minority (<1%) of cases and this did not justify retaining dulaglutide on the NCL Joint Formulary. The Committee upheld their original decision to removed dulaglutide as an option for routine use however specialists could apply to use dulaglutide on an individual patient basis, provided the patient has exceptional circumstances, with approval sought from Trust Drugs & Therapeutics Committees, Medicines Management Teams or GPs (whichever is most appropriate).

**Decision:** Removed from the NCL Joint Formulary. Specialists can apply for dulaglutide on an individual patient basis, provided the patient has exceptional circumstances.

**5. JfC Work Plan & outstanding actions**

These items were included for information only. Any questions should be directed to Ms Kassam.

**6. Declarations of relevant conflicts of interest**

The Committee acknowledged Dr Cohen's declared conflicts of interest as part of item 4.1. No additional declarations were noted for the new medicine applications.

**7. Local DTC recommendations / minutes****7.1 Approved**

| DTC site | Month  | Drug   | Indication  | JfC outcome  |
|----------|--------|--|---|--|
| UCLH     | Mar-19 | MultiHance®  | Detection of hepatocellular carcinoma & liver metastases  | Decision: Approved<br>Prescribing: UCLH only<br>Tariff status: In tariff<br>Funding: Trust<br>Fact sheet or shared care required: No |
| UCLH     | Mar-19 | Olaparib - Pre-NICE free of charge scheme [GID-TA10257]  | Maintenance therapy in gynaecological cancer after response to first-line platinum based chemotherapy   | Decision: Approved<br>Prescribing: UCLH only<br>Tariff status: N/A<br>Funding: FoC<br>Fact sheet or shared care required: No         |
| UCLH     | Mar-19 | Rucaparib - Pre-NICE free of charge scheme [GID-TA10383] | Maintenance therapy in gynaecological cancer for patients in response to at least two previous lines of platinum-based chemotherapy who do not meet the criteria for maintenance niraparib (via CDF) or maintenance olaparib (NICE TA381) therapy | Decision: Approved<br>Prescribing: UCLH only<br>Tariff status: N/A<br>Funding: FoC<br>Fact sheet or shared care required: No         |

|               |          |                              |   |  |
|---------------|----------|------------------------------|---|--|
| UCLH          | Mar-19   | Levobupivacaine<br>0.125% IV | Paravertebral block   | Decision: Approved<br>Prescribing: UCLH only<br>Tariff status: In tariff<br>Funding: Trust<br>Fact sheet or shared care<br>required: No  |
| UCLH          | Mar-19   | Metformin                    | Polycystic ovary syndrome   | Decision: Added to NCL Joint<br>Formulary<br>Prescribing: Primary and<br>secondary care<br>Tariff status: In tariff<br>Funding: Trust<br>Fact sheet or shared care<br>required: No         |
| RFL           | Mar-19   | Dupilumab EAMS<br>scheme     | Atopic eczema   | Decision: Approved<br>Prescribing: GOSH and RFL<br>Tariff status: Excluded<br>Funding: FoC<br>Fact sheet or shared care<br>required: No  |
| Camden<br>CCG | Pre-2012 | Nortriptyline                | Prophylaxis of tension<br>headache                                  | Decision: Added to NCL Joint<br>Formulary<br>Prescribing: Primary and<br>secondary care<br>Tariff status: In tariff<br>Funding: Trust and CCG<br>Fact sheet or shared care<br>required: No |
| Camden<br>CCG | Pre-2012 | Verapamil                    | Prophylaxis of cluster<br>headache                                  | Decision: Added to NCL Joint<br>Formulary<br>Prescribing: Primary and<br>secondary care<br>Tariff status: In tariff<br>Funding: Trust and CCG<br>Fact sheet or shared care<br>required: No |
| UCLH          | Pre-2012 | Pancrex V powder             | Pancreatic enzyme deficiency<br>To unblock enteral feeding<br>tubes | Decision: Added to NCL Joint<br>Formulary<br>Prescribing: Secondary care<br>Tariff status: In tariff<br>Funding: Trust<br>Fact sheet or shared care<br>required: No                        |

## 7.2 Under evaluation

| DTC site | Month  | Drug       | Indication   | JfC outcome   |
|----------|--------|------------|--|---|
| UCLH     | Mar-19 | Primovist® | MRI contrast for liver imaging<br>(including detection of<br>hepatocellular carcinoma &<br>liver metastases) | Decision: Approved under 6<br>month evaluation<br>Prescribing: UCLH only<br>Tariff status: In tariff<br>Funding: Trust<br>Fact sheet or shared care<br>required: No |

|     |        |                    |                           |   |
|-----|--------|--------------------|---------------------------|---|
| RFL | Mar-19 | Plenvu® FoC scheme | Bowel cleansing treatment | Decision: Under evaluation<br>Prescribing: RFL only<br>Tariff status: In tariff<br>Funding: Trust<br>Fact sheet or shared care required: No |
|-----|--------|--------------------|---------------------------|---|

## 8. New Medicine Reviews

### 8.1 Evaluation: Apixaban for cancer thromboprophylaxis (Applicant: Dr M Thomas, UCLH)

The Committee heard three proposals for the evaluation of apixaban for the prophylaxis of venous thromboembolism (VTE) in patients with:

- Multiple myeloma starting chemotherapy with thalidomide, lenalidomide or pomalidomide who would previously have received LMWH
- Newly diagnosed multiple myeloma with additional VTE risk factor
- Newly diagnosed pancreatic cancer receiving chemotherapy
- Newly diagnosed cholangiocarcinoma receiving chemotherapy
- Newly diagnosed Stage III or IV ovarian cancer receiving neo-adjuvant chemotherapy before interval debulking surgery at intermediate to high risk for VTE (Khorana score  $\geq 2$ )

NICE guidance does not recommend the routine use of thromboprophylaxis in ambulatory patients with cancer, but suggest thromboprophylaxis with low molecular weight heparin (LMWH) may be considered in patients with pancreatic cancer undergoing chemotherapy or in patients with myeloma who are receiving therapy with thalidomide, lenalidomide or pomalidomide and steroids. Currently, practice in NCL is to not offer thromboprophylaxis in patients with pancreatic cancer, cholangiocarcinoma or pre-operative ovarian cancer. Patients with myeloma receiving thalidomide or lenalidomide undergo a VTE risk assessment and are considered for thromboprophylaxis with aspirin, prophylactic or treatment dose LMWH.

The Committee therefore considered three requests:

- Apixaban as an alternative to LMWH for thromboprophylaxis (where currently indicated) in patients with cancer
- Thromboprophylaxis for patients with pancreatic cancer (NICE states “consider” for this group)
- Thromboprophylaxis for patients with cholangiocarcinoma or stage III or IV ovarian cancer receiving neo-adjuvant chemotherapy before interval debulking surgery (not considered by NICE)

Two randomised, placebo controlled trials evaluated the use of a direct factor Xa inhibitor in patients at intermediate to high risk of VTE (Khorana score  $\geq 2$ ) and receiving chemotherapy. Both trials included mixed cancer types, a high proportion of patients with gynaecologic and pancreatic cancer patients were included in the AVERT trial, and a high proportion of patients with pancreatic cancer were included in the CASSINI trial; patients with multiple myeloma were under-represented. The AVERT study showed apixaban lowered the rate of symptomatic VTE versus placebo (absolute risk reduction 6%; HR = 0.41 [95% CI: 0.26 to 0.65]) driven predominately by lower rate of pulmonary embolism with an increased risk of major bleed (absolute increase of 1.7%; HR = 2.0 [95% CI: 1.01-3.95]) and clinically relevant bleeds (absolute increase of 1.8%; HR = 1.28 [95% CI: 0.89-1.84]). The CASSINI study showed that rivaroxaban had no significant effect on VTE (HR = 0.66 [95% CI: 0.40 to 1.09]) and had a non-statistically significant increase in major bleed (absolute increase of 1%; HR = 1.96 [95% CI: 0.59 to 6.49]).

The Committee reviewed a local update of the Cochrane review of different pharmacological interventions on the rate of VTE and bleeding in ambulatory cancer patients receiving chemotherapy. Pooled analysis of the CASSINI and AVERT studies showed direct oral anticoagulants (DOACs) were not superior to placebo in terms of reducing symptomatic VTE (RR = 0.57 [95% CI: 0.29 to 1.14]) or symptomatic PE (RR = 0.53 [95% CI: 0.13 to 2.10]) whereas LMWH was superior for both outcomes (RR = 0.61 [95% CI: 0.41 to 0.89] and 0.61 [95% CI: 0.41 to 0.89] respectively). Both DOACs and LMWH were associated with an increase in major bleeding, with DOACs trending worse than LMWH (RR = 1.95 [95% CI: 0.88-4.30] and RR = 1.49 [95% CI: 0.86-2.59] respectively). Conclusions from this analysis were LMWH were preferred in terms of safety and efficacy given the available evidence.

The number needed to treat (NNT) to avoid one symptomatic PE or incidental/symptomatic VTE was 20 and the number needed to harm (NNH) for major bleed was 59 (AVERT trial). The associated cost to prevent one symptomatic PE or incidental/symptomatic VTE with apixaban was estimated to be

approximately £6,600 versus £2,500-£4,400 with a LMWH. The total budget impact if the three evaluations were approved was estimated to be approximately £120,000 (per annum) across NCL; the incremental cost difference compared to LMWH would be £45,000-£75,000.

Dr Thomas suggested that the AVERT trial provides reassurance on the efficacy and safety of apixaban in this patient population. Although DVTs are rarely fatal they cause distress, interrupt cancer treatment and delay surgery/chemotherapy, therefore thromboprophylaxis is warranted in these patient groups. The use of thromboprophylaxis is recommended by international guidelines in high risk patients; as such the proposal for ovarian cancer included a Khorana score  $\geq 2$  (intermediate to high risk), to identify high risk patients. The applicant acknowledged NICE did not consider the Khorana scale to be sufficiently sensitive to recommend its use in routine clinical practice, however in the applicant's view the tool was the best available. The Committee heard cholangiocarcinoma was a rare cancer with a very high risk of VTE. The proposed ovarian cancer indication identified a population at high risk in local audit data, probably due to the pelvic mass, concurrent chemotherapy and active cancer diagnosis which are all VTE risk factors. The Committee discussed the issue of equipoise in the design of the DOAC trials, in order to better contextualise the data. To the generalist, the LMWH data in ambulant patients undergoing chemotherapy provided evidence of an overall beneficial effect of anticoagulation. In the design of other anticoagulation trials, LMWH appeared to be the standard of care against which new therapies ought be compared in head-to-head trials, rather than placebo. However the DOAC trials were performed against placebo. This implied to the Committee that the cancer community remained in equipoise on this matter; anticoagulation is as likely to be harmful as beneficial in these patients (otherwise placebo-controlled trials would be deemed unethical). Since the data from the DOAC trials was even less persuasive than the LMWH data, the Committee did not see how the position of equipoise could be abandoned at this time, so dampening the enthusiasm for adopting DOACs for these indications.

*In camera*, the Committee was satisfied that all four cancer types were at sufficiently high risk to justify offering thromboprophylaxis to patients. In terms of the recommended treatment, the Committee acknowledged patient preference for an orally administered medication compared to daily SC injections, however the evidence-base for DOACs was considered less convincing than for LMWH at the current time. There was an additional concern that inappropriate continuation of thromboprophylaxis after cessation of chemotherapy was more likely with DOACs than LMWH, exposing patients to the risks of bleeding for no benefit. On balance, the Committee was only able to justify the additional cost and risk reduction for patients who require thromboprophylaxis in the very long term where daily SC LMWH injections would cause compliance issues.

In summary, apixaban and LMWH were recommended as treatment options for patient with multiple myeloma receiving chemotherapy with thalidomide, lenalidomide or pomalidomide and steroids. LMWH alone was recommended for patients newly diagnosed pancreatic cancer or cholangiocarcinoma receiving chemotherapy and newly diagnosed Stage III or IV ovarian cancer receiving neo-adjuvant chemotherapy before interval debulking surgery at intermediate-high risk for VTE (Khorana score  $\geq 2$ ).

**Decision:** Apixaban: approved for patients with multiple myeloma starting chemotherapy with thalidomide, lenalidomide or pomalidomide who would previously have received LMWH; and newly diagnosed multiple myeloma with additional VTE risk factor.

**Prescribing:** Secondary care only

**Tariff status:** In tariff

**Funding:** Trust

**Fact sheet or shared care required:** No

**Additional information:** Dose is 2.5mg BD.

**Decision:** LWMH: approved for newly diagnosed pancreatic cancer or cholangiocarcinoma receiving chemotherapy and newly diagnosed Stage III or IV ovarian cancer receiving neo-adjuvant chemotherapy before interval debulking surgery at intermediate-high risk for VTE (Khorana score  $\geq 2$ )

**Prescribing:** Secondary care only

**Tariff status:** In tariff

**Funding:** Trust

**Fact sheet or shared care required:** No

**Additional information:** Dose is usual prophylactic dose (e.g. enoxaparin 40mg daily, dalteparin 5,000 unit daily)

### 8.2 Catephen® for treatment of external genital and perianal warts (Applicant: Dr S Aung, NMUH)

The Committee considered an application in absentia for Catephen (camelia sinensis 10%) for the treatment of anogenital warts. The applicant had requested Catephen in part due to a shortage of Warticon® cream (podophyllotoxin 0.15%), which is a regularly used as first-line treatment. BASHH guidelines suggest Catephen, podophyllotoxin preparations (liquid and cream), imiquimod and surgical interventions are all suitable options for the treatment of external genital and perianal warts with no comparative data to suggest superiority of any one treatment. 'No treatment' is also an option as the condition is self-limiting.

A NICE Evidence Summary included a pooled analysis of two randomised controlled trials (n=1,005) which identified that Catephen ointment resulted in complete clearance of all baseline and newly developed genital and perianal warts in 53.6% of patients compared to 35.4% of patients using [placebo] vehicle ointment (OR 2.10 [95% CI: 1.49 to 2.98]). Similar differences were seen in the clearance of baseline warts only. Catephen demonstrated significantly higher clearance of all warts versus vehicle ointment from week 6 of treatment and throughout the remainder of the 16-week period. More people in the Catephen group experienced severe local reactions compared to vehicle.

Catephen was indirectly compared against other treatments available in NCL with no evidence of superiority observed. A disadvantage of the product was higher treatment cost compared to all alternatives and an increased frequency of application which may not be preferred by patients. The Committee concluded that Catephen offered no improvement in efficacy versus other therapies and there was insufficient unmet clinical need for further lines of therapy.

In summary, the Committee did not approve Catephen for the treatment of genital and perianal warts.

**Decision:** Not approved

### 8.3 EAMS: Atezolizumab + nab-paclitaxel for the treatment of unresectable locally advanced or metastatic triple-negative breast cancer (Applicant: Dr J Newby, RFL)

The Committee considered an application for atezolizumab in combination with nab-paclitaxel for the treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC) whose tumours have PD-L1 expression  $\geq 1\%$  and who have not received prior chemotherapy for their metastatic disease under an EAMS.

Impassion130 was a Phase III, double-blind, randomised controlled trial to assess the safety and efficacy of atezolizumab and placebo, both in combination with nab-paclitaxel, in patients with unresectable locally advanced or metastatic TNBC. Atezolizumab showed a modest, statistically significant increase in progression free survival (PFS) over placebo (7.2 vs. 5.5 months; HR = 0.80 [95% CI: 0.69 to 0.92]), with a non-significant trend towards improved overall survival (OS) (21.3 vs. 17.6 months; HR = 0.84 [95% CI: 0.69 to 1.02]). In a pre-specified subset analysis in patients with PD-L1 expression, atezolizumab improved PFS (7.5 versus 5.0 months; HR = 0.62 [95% CI: 0.49 to 0.78]) and OS (25.0 versus 15.5 months; HR = 0.62 [95% CI: 0.45 to 0.86]).

Grade  $\geq 3$  adverse events occurred in patients receiving atezolizumab than placebo (48.7% vs. 42.2%). There were 3 treatment-related deaths among the 451 patients who received atezolizumab (due to autoimmune hepatitis, mucosal inflammation, and septic shock) and 1 treatment related death in a patient receiving placebo (due to hepatic failure).

Quality of life was not reported although it was a secondary endpoint in the trial protocol. The Committee considered that PFS may improve patient outlook however it was not a reliable proxy for QoL. Due to the marginal and uncertain survival benefit, any negative effect on QoL was considered important, especially as the study authors had omitted these results from the main paper.

In summary, the Committee agreed to add the combination of atezolizumab and nab-paclitaxel (EAMS) for the treatment of unresectable locally advanced or metastatic triple-negative breast cancer, subject to confirmation that QoL measurements for patients in the atezolizumab arm were not worse than in the placebo arm

**Post-meeting note:** The study authors provided a conference abstract reporting that QoL in the Impassion130 trial was not worse in the atezolizumab arm.

**Decision:** Approved

**Prescribing:** Secondary care only

**Tariff status:** NHSE

**Funding:** Nab-paclitaxel and atezolizumab are FoC. PD-1L testing is billable to NHSE (cost/test: £163.51)

**Fact sheet or shared care required:** No

#### 8.4 Proposal to remove eflornithine (Vaniqa®) from the NCL Joint Formulary

The Committee considered an application for the removal of eflornithine for facial hirsutism from the NCL Joint Formulary. Eflornithine is used by endocrinologists and dermatologists at RFL and NMUH for hirsutism related to polycystic ovary syndrome. This application follows a recommendation by PrescQIPP that eflornithine is a 'drug of low priority' and should not be used for the majority of women with facial hirsutism.

Two multicentre, double-blind, randomised [placebo] vehicle controlled trials assessed the efficacy of eflornithine in preventing hair growth. Clinical success was defined as "clear/almost clear" or "marked improvement" via a physician's global assessment by week 24; eflornithine was clinically successful more frequently than with vehicle cream (32% vs. 9%;  $p < 0.05$ ). Limitations of the studies include absence of a power calculation, insufficient information on randomisation & lack of an active comparator. A secondary analysis of patient reported outcomes exhibited significantly 'less bother and discomfort' amongst eflornithine users versus vehicle cream users (29.6% versus 13.8%,  $p < 0.01$ ) however this finding is highly uncertain due to the unexplained absence of data from 86 patients from the original trials.

Clinicians at RFL wished to retain eflornithine on the NCL Joint Formulary for use in a subset of patients who suffer from facial hirsutism despite self-care and lifestyle measures and cannot use first-line co-cyprindiol (such as where the oestrogen content is not appropriate for the patient). This was in line with recommendations from PrescQIPP. PrescQIPP also recommend reviewing eflornithine at four months post initiation with a view to discontinuing treatment if no clinical benefit is perceived.

The Committee recommended restricting eflornithine in line with PrescQIPP recommendations and specialists should be asked to comment on this restriction.

Eflornithine is currently prescribed in primary care under a Shared Care agreement (originally developed by RFL) however the Committee agreed it was appropriate to remove this guideline and replace with a simpler Fact Sheet alongside comprehensive communication from the specialist to GP.

**Action: Confirm that clinicians across NCL are accepting of the restricted use of eflornithine:**

1. **Used after failure of self-care and lifestyle measures**
2. **Used in individuals in whom alternatives are contra-indicated, ineffective or considered inappropriate**
3. **Acute Trust clinicians to retain prescribing until review point at four months; then to transfer to Primary Care**

#### 9. Request to use Relvar Ellipta for patients aged 12-17 years with Asthma

The Committee were informed that paediatrics at WH would like to use Relvar Ellipta (a combination fluticasone/vilanterol inhaler) in patients aged 12-17 years with asthma as an alternative to Seretide. Evidence for this cohort of patients was heard at JfC in 2014. However, the therapy was rejected based on concerns of generic combination inhalers entering the market. JfC later approved the inhaler for asthma in the adult population in October 2016. The Committee were satisfied that the evidence submitted previously was inclusive of this population with minimal cost difference in treatments. In summary, Relvar Ellipta was added to the Joint Formulary for use in patients aged 12-17 years with asthma.

**Decision:** Approved (patients aged 12-17)

**Prescribing:** Primary and Secondary Care

**Tariff status:** In Tariff

**Funding:** Hospital/CCG

**Fact sheet or shared care required:** No

#### 10. VSL#3® formulary status after removal from ACBS list

The Committee were informed that ACBS have removed their endorsement of two probiotics VSL#3® and Vivomixx® for the maintenance of remission of pouchitis. JfC Support engaged with ABCS and learnt their decision was based on the NHSE 'Items not for routine prescribing in primary care' work which

recommended against the use of probiotics, the lack of evidence to support their efficacy and that the review of products with a medicinal claim was outside the ACBS' remit.

JfC added VSL#3 to the NCL Joint Formulary for use in patients with pouchitis in 2013 and there have been no relevant trials published subsequently. The PSNC had confirmed that VSL#3 can still be prescribed in primary care as it is not black-listed and the UCLH IBD team wished to continue prescribing VSL#3. The Committee therefore agreed VSL#3 should remain on the formulary for patients with pouchitis as per the initial JfC decision; if this is considered inappropriate a deprescribing application should be submitted.

Mr Dutt asked for confirmation from NHSBSA that primary care will be reimbursed, if this is not the case JfC will consider further.

**Action: Mr Dutt to confirm with NHSBSA that primary care will be reimbursed for VSL#3**

## **11. Next meeting**

Monday 17<sup>th</sup> June 2019, 4.30 – 6.30pm, Venue: LG01, 222 Euston Road, London, NW1 2DA

## **12. Any other business**

### **12.1 Fulvestrant for breast cancer**

JfC had approved fulvestrant in 2016 as third-line therapy (after non-steroidal aromatase inhibitor and tamoxifen) for locally advanced or metastatic breast cancer. NICE TA529 recommends abemaciclib with fulvestrant as second-line therapy (after non-steroidal aromatase inhibitor). The following update of the formulary status for fulvestrant was provided:

Clarification of JfC decision from 2016:

- As monotherapy; as third-line therapy for locally advanced or metastatic HER2-, ER+ breast cancer in postmenopausal women without symptomatic visceral disease, that has recurred or progressed after a non-steroidal aromatase inhibitor and tamoxifen
- In tariff

NICE TA529:

- In combination with abemaciclib; as second-line therapy for advanced HER2-, ER+ breast cancer in postmenopausal women without symptomatic visceral disease, that has recurred or progressed after a non-steroidal aromatase inhibitor
- Funded by CDF

### **12.2 Erenumab for prophylaxis of chronic migraine**

Ms Samuels informed the Committee that a sub-set of patients who had either failed, or were contraindicated to, botulinum toxin will be recruited to the erenumab pre-NICE FoC scheme following the publication of a positive NICE FAD for prophylaxis of chronic migraine, as per JfC decision in January 2019.

### **12.3 Declarations of interest (DOI) for new drug applications**

The Committee agreed not to consider new drug applications without completed declarations of interests. Ms Spicer recommended for the DOI field appear at the beginning of the JfC form.

DOIs from applicants would be circulated in the JfC agenda for the Committee to review in advance of the meeting.

**Action: JfC Support to update the Joint Formulary application forms**