**Northern, Eastern and Western Devon Clinical Commissioning Group**
**South Devon and Torbay Clinical Commissioning Group**

# Clinical Policy Committee (CPC)
# Minutes

**Wednesday 5th March 2014, 14.00-16.00**

**Room 3, The Hayridge Centre Cullompton, EX15 1DJ**

**Present**:

| | | |
|---|---|---|
| Dr Jo Roberts* (Chair) | GP Clinical Commissioner | South Devon & Torbay CCG |
| Dr Mick Braddick* | GP Clinical Commissioner | NEW Devon CCG |
| Dr Andrew Craig* | GP Clinical Commissioner | NEW Devon CCG |
| Richard Croker* | Head of Medicines Optimisation | NEW Devon CCG |
| Paul Foster | Chief Pharmacist | SDHC NHS FT |
| Dr Andrew Gunatilleke | Consultant in Pain Management & Anaesthesia | SDHC NHS Foundation Trust |
| Dr Phil Melluish* | GP Clinical Commissioner | South Devon and Torbay CCG |
| Mac Merrett | Lay Member | |
| Chris Roome | Head of Clinical Effectiveness | NEW Devon CCG |
| Dr Alison Round* | GP Clinical Commissioner | NEW Devon CCG |
| Alison Wilkinson | Head of Contracting and Business Intelligence | NEW Devon CCG |

**Guests**:

| | | |
|---|---|---|
| Dr Richard Haigh | Consultant Rheumatologist | Royal Devon and Exeter NHS FT |
| Hilary Pearce | Clinical Effectiveness Pharmacist | NEW Devon CCG |

**In attendance**:

| | | |
|---|---|---|
| Fiona Dyroff | Clinical Effectiveness Governance Support Officer | NEW Devon CCG |
| Rebecca Heayn | Clinical Effectiveness Governance Manager | NEW Devon CCG |

* Denotes voting members

## 1. Welcome and introductions

Attendees were welcomed to the meeting
Dr Darunee Whiting had delegated voting authority to Richard Croker for this meeting.
Dr Andy Craig attended the meeting via teleconference.

**Apologies**

| | | |
|---|---|---|
| Sue Baldwin | Patient Safety and Quality | NEW Devon CCG |
| Tawfique Daneshmend | Consultant in Gastroenterologist & Hepatologist | RD&E NHS FT |
| Dr Keith Gillespie | GP Clinical Commissioner | NEW Devon CCG |
| Dr Stephen Hunt | GP Clinical Commissioner | NEW Devon CCG |
| Andrew Kingsley | Patient Safety and Quality | NEW Devon CCG |
| Tracey Polak | Assistant Director/Consultant in Public Health | Devon County Council |
| Dr Darunee Whiting | GP Clinical Commissioner | NEW Devon CCG |

**Confirmation of voting members and Declarations of Interest**

The six voting members present were noted.

Declaration of interest forms were collected. The Chair informed the committee of the declarations of interest received.

| DRUG/TECHNOLOGY TO BE CONSIDERED | PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER |
|---|---|
| **Certolizumab** (Cimzia®) | **UCB Pharma** |
| Alternative treatments:<br>**Adalimumab** (Humira®)<br>**Etanercept** (Enbrel®)<br>**Golimumab** (Simponi®) | <br>**AbbVie**<br>**Pfizer**<br>**Merck Sharp & Dohme** |
| **Bevacizumab** (unlicensed NHS special) | |
| Alternative treatments:<br>**Ranibizumab** (Lucentis®) | <br>**Novartis** |

| NAME OF ATTENDEE | ROLE | |
|---|---|---|
| Dr Andrew Gunatilleke | Consultant in Pain Management & Anaesthesia | Received funding to go to World Pain Congress in Edinburgh – 2008 (Pfizer) |
| Dr Richard Haigh | Consultant physician | Advisory Board UCB: Cimzia in rheumatoid arthritis 2011<br>Various pharmaceutical/manufacturing companies sponsor refreshments & catering at regional national rheumatology scientific educational meetings attended over the last 3 years. |
| Dr Jo Roberts | GP Commissioner | Meeting with Astra Zeneca leadership team<br>Meeting with Janssen Senior leadership discussion regarding partnership working |

**Notification of Any Other Business**

The chair asked the committee if there were any items to be discussed under AOB.

## 2. Minutes of the meeting held on 20th November 2013 and matters/actions arising

The minutes of the meeting held on 20th November were approved.

Actions from the previous meeting:

13/42 Revised Terms of Reference to be taken to CCGs' governing bodies for noting and agreement.

Action complete

13/43 Appeals process to be taken to CCGs governing bodies for noting and agreement.

Action complete

13/44 Details of identified South Devon and Torbay CCG appeals panel members to be provided.

No reply has been received to date. This will be followed up.

13/45 Linaclotide for the treatment of Irritable Bowel Syndrome commissioning policy to be published.

Action complete

13/46 Issues around CCG decision making capacity to be raised with South Devon and Torbay CCG.

Action complete

## 3. Certolizumab pegol for psoriatic arthritis

An application had been received requesting the inclusion of certolizumab into local formularies as a first line biological agent for the treatment of psoriatic arthritis in line with existing NICE recommended treatment options. The committee were asked to consider the evidence. Hilary Pearce, Clinical Effectiveness Pharmacist, presented an evidence review. Dr Richard Haigh, Consultant Rheumatologist was present for this item and represented rheumatologists from three acute trusts in Devon.

NICE recommends four anti-TNFs as treatments for psoriatic arthritis, they do not appear to have any plans to review certolizumab. In December 2013 certolizumab in combination with methotrexate was licensed for treating psoriatic arthritis when the response to previous disease modifying anti-rheumatic drugs (DMARD) therapy has been inadequate. Certolizumab can be given as monotherapy. Certolizumab is administered by subcutaneous (sc) injection. Following loading doses, the dose is 200mg every two weeks. Once clinical response is confirmed a maintenance dose of 400mg every four weeks can be considered. A commercially confidential patient access scheme exists for certolizumab which makes certolizumab less expensive than the other agents.

The committee reviewed the evidence for commissioning certolizumab for this indication. One well conducted randomised controlled trial had been published. This is an on-going 216 week trial which is double-blind and placebo-controlled to week 24. The trial achieved its clinical primary endpoint of ACR20 response at week 12. Statistically significant differences from placebo were also seen for both dose groups in ACR50 and ACR70 responses. The effectiveness of certolizumab was demonstrated for several endpoints relevant to the arthritic and psoriatic components of psoriatic arthritis.

Given the reduced acquisition cost for certolizumab compared with other anti-TNFs and the outcomes from the certolizumab trial, it is reasonable to assume that certolizumab would be a

cost-effective option given the trial evidence, cost-effectiveness analysis and decisions supporting the recommendations from NICE TA199 and TA220.

The committee considered a range of issues pertinent to this therapy:

- The maintenance dosing regimen to be used in clinical practice was discussed. Dr Haigh indicated that he would prescribe certolizumab every two weeks because of its short half life.
- The relative short term data that are available. Dr Haigh explained that the availability of effective treatments has made long term placebo-controlled trials unethical.

The committee voted unanimously in favour of commissioning certolizumab for the treatment of psoriatic arthritis.

**ACTION: Commissioning policy to be published.**

The committee also discussed difficulties for primary care when up to date records of the drugs taken by a patient were not easily available.

## 4. Certolizumab Pegol for ankylosing spondylitis

An application had been received requesting the inclusion of certolizumab into local formularies as a first line biological agent for the treatment of ankylosing spondylitis in line with existing NICE recommended treatment options. The committee were asked to consider the evidence for commissioning certolizumab for the treatment of ankylosing spondylitis. Hilary Pearce, Clinical Effectiveness Pharmacist, presented an evidence review. Dr Richard Haigh, Consultant Rheumatologist was present for this item.

NICE recommends three anti-TNFs to treat ankylosing spondylitis. Certolizumab is licensed for treating rheumatoid arthritis and was recently licensed for the treatment of ankylosing spondylitis. NICE are conducting a multiple technology appraisal of anti-TNFs, including certolizumab for this indication. Certolizumab is administered by sc injection; the starting dose for adults is 400 mg at weeks 0, 2 and 4. The maintenance dose is 200 mg every 2 weeks or 400 mg every 4 weeks. A commercially confidential patient access scheme exists for certolizumab which makes certolizumab less expensive than the other agents.

The committee reviewed the evidence for commissioning certolizumab for this indication. One phase III RCT was identified. This is an on-going 204 week study which is double-blind and placebo-controlled to week 24. The trial investigated the use of certolizumab for the broader indication of axial spondyloarthritis and included a subgroup of 178 patients who met the criteria for ankylosing spondylitis. The review focused on this subgroup of patients. The clinical primary endpoint of ASAS20 at week 12 assessed for the total study population was met. A similar response rate was achieved for the ankylosing spondylitis subgroup. The effectiveness of certolizumab for the treatment of ankylosing spondylitis was also demonstrated for disease activity endpoints and outcomes relating to function and spinal mobility.

There are no published cost-effectiveness analysis for certolizumab. Review of the certolizumab trial outcomes and the trial evidence and cost effectiveness analysis supporting NICE TA143 and TA 233 suggests that the response rate to treatment for certolizumab would be similar to other NICE recommended anti-TNFs but there is some uncertainty in the difference in health state utilities achieved with the different agents. This needs to be weighed against the reduced acquisition cost of certolizumab compared with other anti-TNFs and the decisions taken by NICE appraisal committees in determining whether a specific anti-TNF would be a cost-effective use of NHS resources.

The committee discussed a range of issues pertinent to this therapy:

- This is long term disease and a 12 week placebo comparison cannot show the full benefits of treatment.

- The NICE MTA is not due to be issued until January 2015. These assessments are sometimes delayed. A commissioning decision is required for the interim period.
- The cost effectiveness of existing drugs have not been robustly compared.

**ACTION: Commissioning policy to be published.**

The committee voted 5 to 1 in favour of commissioning certolizumab for the treatment of ankylosing spondylitis.

## 5. Bevacizumab for pathological myopia

A local policy on anti-VEGFs for the treatment of choroidal neovascularisation (CNV) secondary to pathological myopia was issued by the Peninsula Health Technology Commissioning Group in September 2010. This was subsequently adopted by NEW Devon CCG and South Devon and Torbay CCG. When the policy was issued neither ranibizumab nor bevacizumab were licenced for the treatment of pathological myopia. Reconsideration of the CCGs' policy on bevacizumab is required in the light of the licensing of ranibizumab and the subsequent NICE TAG issued in November 2013 which recommends ranibizumab for CNV due to pathological myopia. All ophthalmologists have indicated that they intend to use the licenced and NICE recommended ranibizumab as first line treatment.

The committee were asked to consider the evidence for bevacizumab as a treatment for CNV due to pathological myopia and determine whether the evidence supports routine commissioning of bevacizumab as an alternative treatment to ranibizumab in situations where specialists consider that ranibizumab would not be the preferred option for their patient. Hilary Pearce, Clinical Effectiveness Pharmacist, presented an evidence review.

Four RCTs were identified. The two trials comparing ranibizumab and bevacizumab, Gharbiya et al (2009) and Iacono et at (2012) were considered to be too small to establish whether a significant difference in efficacy existed between the two therapies. The Gharbiya study was considered to have more methodological limitations than the Iacono study. The RADIANCE study compared ranibizumab with Photodynamic Therapy (PDT), the results supported licensing ranibizumab for pathological myopia. The pilot study by Parodi et at compared bevacizumab with PDT, this trial had a number of methodological limitations. The evidence for bevacizumab for treatment of pathological myopia is less robust than the evidence for ranibizumab. However, data suggests that treatment with bevacizumab shows similar effects to ranibizumab with stabilization, or in many cases, a gain in visual acuity which is maintained in the long term and stabilization of CNV leakage. There were no reports of significant ophthalmic adverse events or systemic adverse events for bevacizumab in the three RCTs investigating bevacizumab. However the studies were too small to draw any conclusions on the safety profile of bevacizumab compared to ranibizumab for this indication. The manufacturer of ranibizumab did not include bevacizumab as a comparator in the cost-effective analysis conducted for TA298.

The committee discussed number of issues pertinent to this therapy.

- Treatment would be expected to consist of 4 to 5 injections over 2 years. Few patients are eligible for ranibizumab and there would be less for bevacizumab.
- The committee considered the options which included rescinding the CCGs' current policy for bevacizumab, offering bevacizumab as an alternative to ranibizumab for use where clinically appropriate, having a policy for bevacizumab as a second line treatment, although it was noted there is no evidence for bevacizumab as second line treatment

The committee voted unanimously in favour of rescinding the CCGs policy on Bevacizumab.

**ACTION: CCGs policy on Bevacizumab to be rescinded.**

## 6. Update from NICE Planning, Quality and Assurance Group (NPAG)

Three NPAG meetings had taken place since the Clinical Policy Committee meeting in November 2013. The committee received an update.

NPAG – 21 January 2014

NICE had recommended three TAs these were:

- TA298 - Ranibizumab for treating choroidal neovascularisation associated with pathological myopia.
- TA300 - Peginterferon alfa and ribavirin for treating chronic hepatitis C in children and young people.
- TA301 - Flucinolone acetonide intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy (rapid review of TA271)

These have been added to formularies.

Public health guidance:

- PH46 – Managing overweight and obesity among children and young people: lifestyle weight management services. Devon County Council's Public Health Team is preparing a communication for primary care.

NPAG - 17 December 2013

NICE had recommended one TA – Ocriplasmin for treating vitreomacular traction (TA297)

NICE had issued clinical guidance on Stroke rehabilitation (CG162) – good responses had been received from all providers. Issues relating to pathways of care involving stroke specialists, community teams and social workers had been identified. In particular a lack of social workers in the western locality had been identified.

NICE had issued medical technology guidance on Ambu aScope2 for use in unexpected difficult airways (MTG14). Responses from local trusts had indicated that this technology was not currently used and that there are no plans to do so.

NICE diagnostic guideline on faecal calprotectin diagnostic tests for inflammatory diseases of the bowel (DG11). NEW Devon CCG will commission the test. The commissioning lead is undertaking some work around the appropriate commissioning pathway.

NPAG – 19 November 2013

NICE had issued clinical guidance on familial breast cancer (CG164). It was noted that both the Peninsula Breast Cancer Group and the Royal College of radiologists disagreed with the guidance. Implementation of the guidance will increase the need for mammography. Implementation of the guidance is currently on hold pending clarification on issues raised by the Peninsula Breast Cancer Group and the Royal College of radiologists.

## 7. Public Involvement – lay membership update

The committee received an update on the progress made since November 2014 on the appointment of additional lay membership to the group. The main points were:

- Mac Merrett had been involved in the development of the role description. Mac and Christine Buswell have agreed to provide lay member support to the process. Christine is a lay member for NEW Devon CCG. It is hoped that a pool of lay members can be set up.

- A press release had been drafted by the CCG's communications team. This had been circulated in the local media, via Healthwatch, Pulse and through social media. A good response had been received.
- The closing date was Friday 28th February 2014. Six applications had been received and interviews will take place at the end of March 2014.

## 8. Any other business

There was no other business to report.

The meeting closed at 12 noon.

**Summary of actions**

| | **Action** | **Lead** |
|---|---|---|
| 13/44 | *Details of identified South Devon and Torbay CCG appeals panel members to be provided*.<br><br>No reply has been received to date. This will be followed up. | Jo Roberts |
| 14/01 | Certolizumab pegol for the treatment of psoriatic arthritis commissioning policy to be published. | Rebecca Heayn |
| 14/02 | Certolizumab pegol for the treatment of ankylosing spondylitis commissioning policy to be published. | Rebecca Heayn |
| 14/03 | Bevacizumab for pathological myopia commissioning policy to be rescinded. | Rebecca Heayn |