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

Meeting of the South and West Devon Formulary Interface Group

Minutes

Wednesday 13 September 2017: 2:00 pm – 4.30 pm

The Watermark, Erme Court, Leonards Road, Ivybridge PL21 0SZ

Present:

Andrew Gunatilleke (Chair)	Consultant	Torbay & South Devon NHS FT
Josh Hamilton	GP	Kernow CCG
Lily Hammarlund Sim	Pharmaceutical Advisor	Kernow CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Paul Manson	Senior MO Pharmacist	NEW Devon CCG
Phil Melluish	GP	South Devon & Torbay CCG
Bill Nolan	GP	South Devon & Torbay CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Iain Roberts	Lead MO Pharmacist	South Devon & Torbay CCG
Christopher Sullivan	Pharmacist	Devon Partnership NHS Trust
Darren Wright	Joint Formularies Technician	NEW Devon CCG

Guests:

Theresa Mitchell	Tissue Viability CNS	Livewell Southwest, Plymouth
Sara Stylianou	Lower Limb Therapy Service Lead	Torbay & South Devon NHS FT

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG

1. Welcome and announcements

Welcome

Attendees were welcomed to the meeting.

Announcements

Jeremy Morris has retired from Plymouth Hospitals NHS Trust. Matt Brindley, Assistant Director of Pharmacy has asked to be copied into meeting papers and may attend FIG meetings when input from secondary care pharmacy is specifically required.

The FIG expressed thanks to Jeremy Morris for all his hard work and input as a member of the FIG.

Apologies

Andy Craig	GP	NEW Devon CCG
Mark Stone	Community Pharmacist	
Nicola Joyce	Principal Pharmacist	Livewell Southwest

Declaration of Interests

No interests were declared.

2. Minutes of the meeting held on Wednesday 12 July 2017 and matters arising

The minutes of the meeting held on Wednesday 12 July 2017 were approved.

Summary of actions

	Action	Lead	Status
17/35	Liothyronine - When available link to host website for specialist protocol for patients receiving liothyronine to be added to the formularies.	Formulary Team	
17/39	Fiasp products entry to be added to the formulary in line with the discussion.	Formulary Team	Complete
17/40	Ralvo® to be added to the formulary as the preferred brand of lidocaine 700 mg (5% w/w) medicated plaster.	Formulary Team	Complete

17/41	Ralvo® to be added to the preferred brand page of the formulary.	Formulary Team	Complete
17/42	Formulary status of prednisolone 10mg/ml oral solution to be amended from (Red) to become a second-line (Blue) preparation.	Formulary Team	Complete
17/43	Formulary section for the management of epilepsy to be updated with the new guidance in line with the discussion.	Formulary Team	Complete
17/44	Emergency contraception guidance: Liaise with Family Planning with regard to rapidity of patient referrals from GPs for IUD.	Formulary Team	Complete
17/45	Update emergency contraception advice formulary guidance in line with the discussion.	Formulary Team	Complete
17/46	Proposed revision to the formulary entry for “Gonadorelin analogues and gonadotrophin-releasing hormone antagonists”: Table for possible inclusion in the formulary to be forwarded to the formulary team at NEW Devon CCG.	Larissa Sullivan	Complete
17/47	Formulary entry for Gonadorelin analogues and gonadotrophin-releasing hormone antagonists” to be updated in line the discussion.	Formulary Team	Complete
17/48	Formulary section for Blood Glucose monitoring in Type 1 diabetes to be updated in line with new guidance.	Formulary Team	Complete
17/49	Additional information for Maintenance and Reliever Therapy (MART) Regimes to be included in the asthma formulary guidance.	Formulary Team	Complete
17/50	Migraine guidance: Northern and Eastern formulary paediatric entry to be send to specialists.	Formulary Team	
17/51	Amendments to be made to the proposed migraine guidance in line with the discussion and sent to Dr Medcalf, Dr Whetherby and pain consultants at Torbay and South Devon NHS Foundation Trust.	Formulary Team	
17/52	Migraine guidance: amended migraine guidance to be brought back to a future meeting for agreement.	Formulary Team	
17/53	On completion of the CCGs governance processes the approved entry for sodium oxybate for the treatment of narcolepsy with cataplexy to be added to the formulary.	Formulary Team	Complete
17/54	On completion of the CCGs governance processes the approved entry for lecicarbon A suppositories for the treatment of constipation to be added to the formulary.	Formulary Team	Complete
17/55	Newsletter update: Newsletter to be forward to Sophie Cottrell.	Formulary Team	Complete

Matters arising

E-FIG Declaration of Interest forms

The e-FIG governance processes have been considered by the Clinical Effectiveness Team. This was particularly with regard to reporting of Declaration of Interests for e-FIG meetings.

The FIG agreed that members responding to e-FIG questions will indicate whether they have any interests to declare in their response. The issues discussed through e-FIG will be included on the DoI form for the next face to face meeting and members should fully report any interests relating e-FIG discussions.

3. Tiotropium bromide monohydrate and olodaterol hydrochloride (Spiolto® Respimat®) combination inhaler for COPD

At its meeting on 26th July 2017 the Clinical Policy Committee (CPC) made a recommendation in favour of routinely commissioning Spiolto Respimat combination inhaler for the treatment of chronic obstructive pulmonary disease (COPD) in adults. The place in therapy for Spiolto Respimat is as an alternative to other LAMA/LABA fixed dose combination inhalers within its licenced indication in patients with COPD in accordance with relevant international, national and local guidance. Points raised by CPC were with regard to the previously issued MRHA safety advice and whether it still applied. The Clinical Effectiveness Team reiterated that MHRA advice reported in the paper still applies with regards to tiotropium and relates to both HandiHaler® and Respimat®.

The FIG discussed and approved the proposed formulary entry. Spiolto® Respimat® will be added to the formulary as a 'green' first line option for the treatment of COPD. Ultibro Breezhaler® is also included in the formulary as a 'green' first line option. Duaklir Genuair® is included in the formulary as a 'blue' second line option. The proposed entry will be added to the formulary on completion of the CCGs' governance process and publication of the commissioning policy.

ACTION: On completion of the CCGs' governance processes, Formulary Team to add the approved entry for Tiotropium bromide monohydrate and olodaterol hydrochloride (Spiolto® Respimat®) combination inhaler for COPD to the formulary

The MRHA safety advice will be highlighted on the formulary and in updates circulated through the usual channels.

4. Consideration of levetiracetam granules in sachets for addition to the formularies

A request has been received from Dr Jonathan Gallichan, epilepsy specialist at Derriford Hospital for the addition of levetiracetam granules in sachets (Desitrend®) to the South and West Devon Formulary for the treatment of epilepsy in some paediatric patients.

A study comparing the UK licensed product, Desitrend® 1000mg granules with film-coated reference tablets containing 1000mg levetiracetam found the granules to be bio-equivalent with the tablets.

Levetiracetam granules are more expensive than generic levetiracetam oral solution and cost saving to Keppra® oral solution. The increase in costs was noted. There was discussion about the difficulties experienced by some paediatric patients with the tablets, due to their size and the solution, due to its bitter taste. It was also noted that the summary of product characteristics (SPC) states that the granules are not adapted for use in infants and children under six. There was also discussion about the place in therapy of the granules.

The FIG approved the addition of levetiracetam granules to the formulary as an amber (specialist initiated) product for paediatric patients who cannot take the tablets and cannot tolerate the solution.

ACTION: Formulary team to add levetiracetam granules to the formulary in line with the discussion.

5. Removal of Alzain® as a preferred brand of pregabalin

The South and West Devon Formulary Interface Group approved the removal of Lyrica® as the preferred brand of pregabalin upon expiry of its patent. Alzain® remained as the preferred brand for all licenced indications. Following the patent expiry, the price of generic pregabalin has dropped so that the acquisition cost of Alzain® is now considerably higher than the August 2017 Drug Tariff price. In addition the manufacturer of Alzain® has rescinded a previously made price promise.

A request has been received from the medicines optimisation (MO) teams of South Devon and Torbay CCG and NEW Devon CCG that the formulary interface group approve the removal of Alzain® from the formulary as the preferred brand of pregabalin in favour of generic prescribing which offers significant cost savings.

The FIG discussed and approved the removal of Alzain® from the formulary as the preferred brand of pregabalin and accepted the proposed formulary entry.

ACTION: Formulary team to remove Alzain® from the formulary as the preferred brand of pregabalin.

ACTION: Formulary team to remove Alzain® from the preferred brand page of the formulary.

There was discussion about the comparative efficacy and potential for misuse of pregabalin. It was agreed that further work was required with Public Health, Devon Partnership NHS Trust and Livewell South West colleagues. Consideration of the issues will be added to the formulary team work plan.

ACTION: Exploration of comparative efficacy and potential for misuse of pregabalin with Public Health, Devon Partnership Trust and Livewell Southwest colleagues to be added to the Formulary Team work plan.

6. Compression hosiery and garments

A review of the Compression hosiery and garments section of the formulary has been undertaken. The South and West Devon Tissue Viability Specialist Nurses have suggested that a new section be added to the formulary to reduce the choices of compression hosiery to a simplified list, making prescribing easier and reducing confusion. Therese Mitchell, Tissue Viability Clinical Nurse Specialist, Livewell Southwest, Plymouth and Sara Stylianou, Lower Limb Therapy Service Lead, Plymouth Hospitals NHS Trust attended the meeting for discussion of this item.

A discussion took place about the benefits of moving from bandages to hosiery. Trials have shown that patients have better healing and fewer recurrences with hosiery and garments than with bandages. The number of products available has been reduced however several products are available giving patients a choice of product to suit their needs and reduce waste. There was also discussion about changes in the delivery of services, prescribing, Wellbeing clubs, the cost per item and value for money.

The FIG accepted the proposed formulary entry for compression hosiery and kits. It was agreed that extra information be provided to aid choice of applicator. It was also agreed that a note be added with regard to the number of items issued. The note will state 'one to wear and one to wash'. Notes will also be added to the entries for Mediven Active® and Mediven® for men socks to aid identification of those suitable for use as sportswear and those suitable for office wear.

The formulary entry includes contact details for Torbay and South Devon NHS Foundation Trust and for Plymouth Hospitals NHS Trust. It was agreed that contact details for East Cornwall be added to the formulary if available.

ACTION: Tissue viability nurses to forward additional information to aid choice of applicators for inclusion in the formulary to Darren Wright.

ACTION: Formulary team to add notes to the formulary entry with regard to the number of items issued and to the entries for Mediven Active® and

Mediven® for men socks to aid identification of those suitable for use as sportswear and those suitable for office wear.

ACTION: Formulary team to add contact details for East Cornwall to the formulary entry if available.

ACTION: Formulary team to add new entry for compression hosiery and garments to the formulary.

7. Antimicrobials and Infections

The Primary Care Antimicrobial Guidance is reviewed annually using Public Health England 'Management of Infection Guidance for Primary Care'.

The FIG reviewed the presented paper. There was discussion about prescribing of products, costs and safety. The proposed South and West Formulary Infections guidance was accepted subject to minor amendment. It was agreed that:

- Fosfomycin - note that 'Doses should be taken preferably before bedtime and after emptying the bladder' to be added to each entry for fosfomycin.
- Uncomplicated UTI in adults
  - Nitrofurantoin – note to see advice below to be added to the MHRA safety update.
  - Pivmecillinam – note to be added regarding penicillin allergy and availability of product.
  - Significant savings can be made if Fosfomycin is prescribed as Monuril®. Script-switch can highlight prescribing of Monuril®
  - The Formulary team will contact micro-biologists at Torbay and South Devon NHS Foundation Trust and also Plymouth Hospitals NHS Trust to check if Pivmecillinam and Fosfomycin are being added to standard sensitivity cultures and to request that Fosfomycin be prescribed as Monuril®.

ACTION: Formulary team to contact micro-biologists at the two acute trusts to check if Pivmecillinam and Fosfomycin are being added to standard sensitivity cultures and to request that Fosfomycin be listed as Monuril®

- UTI in pregnancy
  - Amoxicillin to be an 'amber' specialist input product.
  - Trimethoprim – must be specific about doses and duration of treatment.
- Genital tract infections
  - Chlamydia trachomatis and epididymitis – Azithromycin – Formulary team will check price of 1g as 2 x 500mg versus 4 x 250mg.

- Oral and dental infections guidance – wording to emphasise that patients should see their dentist. If a patient cannot see a dentist recommended medications should be provided.
- Link to patient information leaflet to be added to the formulary.

The formulary team will make the agreed changes to the formulary entry. These will be highlighted in the Medicines Optimisation Post and sent to Mark Stone to ensure stock availability.

ACTION: Formulary team to update formulary entry in line with discussion and add link to patient information leaflet.

8. Denosumab guidance

Denosumab is included in the South and West Devon formulary for the prevention of osteoporotic fractures in postmenopausal women, in line with NICE TA204 and for the prevention of skeletal-related events in adults with bone metastases from solid tumours in line with NICE TA265.

A request has been received for clarification of the current formulary guidance on the use of denosumab as some of the recommendations appear to be contrary to the more recent SMS guidance. Consequently, formulary guidance on monitoring has been removed or reduced in the formulary guidance as it is included in the SMS guideline.

The FIG considered the proposed (revised) formulary osteoporosis guidance for primary prevention of fragility fractures and the proposed formulary osteoporosis guidance for secondary prevention of fragility fractures together with the proposed (revised) drug monograph (6.6.2 Bisphosphonates and other drugs affecting bone metabolism). The FIG accepted the proposed amended formulary entry with minor amendments. A line will be added to the entry for Denosumab (Prolia®) for the primary prevention of fragility fractures and for the entry for the secondary prevention of fragility fractures that this will be a 'red' specialist only product in Torbay.

ACTION: Formulary team to update denosumab guidance in line with the discussion.

9. Management of low back pain and sciatica

Following the publication by NICE of Clinical Guidance (NG59) in November 2016 the formulary team were asked to consider inclusion of brief guidance in the joint formulary. Devon Referral and Support Services are developing referral guidance. It is intended that these documents will complement each other.

There was discussion about non pharmacological alternatives for the treatment of back pain and sciatica. It was noted that non pharmacological alternatives are

provided by Mount Gould and Spring Back in Plymouth. Contact/referral details will be added to the formulary entry. There was also discussion about the need for the guidance to state that opioid use must be intermittent and not regular. It was agreed that a note be added to the formulary entry advising that opioid use should be intermittent.

The FIG accepted the guidance for addition to the formulary with minor amendments.

ACTION: Formulary team to add contact/referral details for Mount Gould and Spring Back to the formulary entry.

ACTION: Formulary team to add note to the formulary entry advising that opioid use should be intermittent.

ACTION: Formulary team to add guidance for the management of low back pain and sciatica to the formulary in line with the discussion.

10. Treatment of pain with opioids

The treatment of pain with opioids guidance section has been reviewed. The guidance pages have been revised and expanded with additional information from the updated 'opioids aware' guidance from the Royal College of anaesthetists' faculty of pain medicines, and local specialist input. Consideration has also been given to the choice of formulary recommended opioids.

The FIG reviewed the guidance pages. The guidance pages were approved without amendment.

A discussion took place, it was noted that there was still work to do regarding the choice of formulary recommended opioids. The FIG reviewed the choice of formulary recommended opioids entries for the treatment of pain using opioids:

- Approximate equivalent doses of opioids – work is ongoing. It was agreed that a line should be added to state that the dose of opioid should not be increased beyond 120mg/24hr. If pain is not controlled doses should not be increased.
- Potency of codeine and tramadol in comparison to stronger opioids – the FIG noted the large genetic variation between individuals in the rate of conversion of codeine to morphine.
- Use of strong opioids – meaning of 'multimodal strategy' to be clarified. Strength to be added to Morphine oral solution. Change the percentage response needed to 30% - 50% throughout.
- Prescribing transmucosal fentanyl preparations – section to be moved to palliative care guidance.
- Treatment of non-malignant pain: Key points - change "correct dose" to "optimal dose". "Multimodal analgesia is more effective than a single agent alone" to be

amended to reflect multiple pharmacological therapies “being” more effective than a single agent alone. Bullet point on multiple drugs to be removed. Link to be added to the opioid pain contract for Kernow CCG and Western Locality NEW Devon CCG. Link to be forwarded to Andrew Gunatilleke.

ACTION: Formulary team to forward link to Kernow CCG and Western Locality NEW Devon CCG Opioid pain contract to Andrew Gunatilleke.

- Opioid use in chronic non-malignant pain -In Steps 1- 4: Add consider use of other pharmacological agents before step 3.
- Change the accepted response rate percentage to be 30-50% reduction in pain’ throughout the document.
- Note to be added stating ‘if the initial dose of opioid was effective but becomes ineffective, consider withdrawal for 2-3 weeks’.
- Check formulary brands throughout document.
- Add contact details for Addaction.

The FIG agreed to review section 4.7.2 Opioid analgesics and section 4.10.3 Opioid dependence and e-mail comments to the formulary team. The formulary team will amend the guidance in line with comments received and circulate to pain and palliative consultants for comments.

ACTION: FIG members to review section 4.7.2 Opioid analgesics and section 4.10.3 Opioid dependence and e-mail comments to the formulary team.

ACTION: Formulary team to update formulary entry in line with the discussion at the FIG meeting and comments received and via e-mail on sections 4.7.2 and 4.10.3

ACTION: Once amended, proposed formulary entry to be circulated to pain and palliative care consultants for comment.

11. Recent drug decisions (including NICE)

Details of the recent drug decisions had been circulated with the meeting papers.

12. MHRA Drug Safety Updates: July and August

July 2017: Daclizumab (Zinbryta) – no action required.

Bendamstine (Levact) – advice for healthcare professionals noted, no action required.

Nivolumab (Opdivo), Pembrolizumab (Keytruda) - advice for healthcare professionals noted, no action required.

August 2017: Ibrutinib (Imbruvica): advice for healthcare professionals noted. No further action required.

Corticosteriods: advice for healthcare professionals noted.

Adrenaline auto-injectors. A discussion took place. This also impacts on other local guidance and work is currently ongoing in this area. A paper will be brought to a future FIG meeting.

ACTION: Formulary team to bring paper to on adrenaline auto-injectors to a future FIG meeting.

Summary of actions

	Action	**Lead**	**Status**
17/35	Liothyronine - When available link to host website for specialist protocol for patients receiving liothyronine to be added to the formularies.	Formulary Team	Pending specialists
17/50	Migraine guidance: Northern and Eastern formulary paediatric entry to be send to specialists.	Formulary Team	Outstanding
17/51	Amendments to be made to the proposed migraine guidance in line with the discussion and send to Dr Medcalf, Dr Whetherby and pain consultants at Torbay and South Devon NHS Foundation Trust	Formulary Team	Outstanding
17/52	Migraine guidance: amended migraine guidance to be brought back to a future meeting for agreement.	Formulary Team	Outstanding
17/56	On completion of the CCGs' governance processes, Formulary Team to add the approved entry for Tiotropium bromide monohydrate and olodaterol hydrochloride (Spiolto® Respimat®) combination inhaler for COPD to the formulary	Formulary Team	Complete
17/57	Levetiracetam granules for the management of epilepsy to be added to the formulary in line with the discussion.	Formulary Team	Complete
17/58	Alzain® to be removed from the formulary as the preferred brand of pregabalin.	Formulary Team	Complete
17/59	Alzain® to be removed from the preferred brand page of the formulary.	Formulary Team	Complete
17/60	Exploration of comparative efficacy and potential for misuse of pregabalin with Public Health and Devon Partnership Trust colleagues to be added to the Formulary Team work plan.	Formulary Team	Complete

17/61	Compression hosiery and garments – additional information on choice of applicator to be forwarded to the formulary team for inclusion in the formulary entry.	Tissue viability nurses	Complete
17/62	Compression hosiery and garments - notes to be added to the formulary entry about the number of items to be prescribed and to the entries for Mediven Active® and Mediven® for men socks to aid identification of sock suitable for use as sportswear and those suitable for office wear.	Formulary Team	Complete
17/63	Compression hosiery and garments: Contact details for East Cornwall to be added to the formulary entry if available. Requested but not currently available.	Formulary Team	Complete
17/64	Approved formulary entry for compression hosiery and garments to be added to the formulary.	Formulary Team	Complete
17/65	Antimicrobials and Infections: Both acute trusts to be contacted for clarification of whether Pivmecillinam and Fosfomycin are being added to standard sensitivity cultures and to request that Fosfomycin be listed as Monuril®	Formulary Team	Complete
17/66	Antimicrobials and Infections: Formulary entry to be updated in line with the discussion and add link to the patient information leaflet.	Formulary Team	Complete
17/67	Denosumab guidance to be updated in line with discussion.	Formulary Team	Complete
17/68	Management of low back pain and sciatica: Contact details/referral details for Mount Gould and Spring Back to be added to the formulary.	Formulary Team	Outstanding
17/69	Management of low back pain and sciatica: Note to be added to the formulary entry advising that opioid use should be intermittent.	Formulary team	Complete
17/70	Guidance for the management of low back pain and sciatica to be added to the formulary in line with the discussion.	Formulary Team	Complete
17/71	Link to Kernow CCG and Western Locality, NEW Devon CCG opioid pain contract to be forwarded to Andrew Gunatilleke.	Formulary Team	Outstanding
17/72	Treatment of pain with opioids: section 4.7.2 Opioid analgesics and section 4.10.3 Opioid dependence to be reviewed and comments e-mailed to the formulary team	FIG Members	On agenda
17/73	Treatment of pain with opioids: Formulary entry to be updated in line with discussions at the FIG meeting and comments received via e-mail from FIG members on sections 4.7.2 and 4.10.3	Formulary Team	Complete
17/74	Treatment of pain with opioids: Amended formulary entry to be circulated to pain and palliative care consultants for comment.	Formulary Team	Complete
17/75	MHRA Drug Safety Updates – August 2017: Adrenaline auto-injectors. Paper to be brought to a future FIG meeting. This has been added to the formulary work stream.	Formulary Team	Complete