A summary of the Joint Prescribing Committee key recommendations following the meeting on 19 June 2013 is provided below:

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| **Lisdexamfetamine dimesylate for ADHD**  
"Approved for use"  
"No GP prescribing until updated shared care guidance is available". | The use of methylphenidate, dexamfetamine and atomoxetine as part of the management of ADHD is supported and locally agreed shared care arrangements are in place. Lisdexamfetamine dimesylate is a newly licensed product indicated for use as part of a comprehensive treatment programme for ADHD in children aged 6 years and over when response to previous methylphenidate treatment is considered clinically inadequate. 

The following recommendations were agreed:-

- The use of lisdexamfetamine dimesylate as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years and over is supported in line with the current positioning (in therapy) of dexamfetamine included in the NICE Clinical Guideline (CG72) on ADHD. (http://guidance.nice.org.uk/CG72/Guidance)
- Prescribing should be initiated by specialist services with GPs taking over prescribing as part of a shared care arrangement.

It was further agreed that the current shared care guideline for drugs used to treat ADHD would be amended. The priority given to the amendment of the guideline would be dependent on the decisions made by SEPT and CCB as initial Specialist response had indicated that GPs may not be asked to share care until the drug was more fully established in the patient pathway. |
| **Lixisenatide for Type 2 Diabetes Mellitus**  
"Approved for use"  
"GP prescribing supported when shared care guidance is available". | Lixisenatide is a GLP-1 mimetic which was launched in the UK in May 2013 and is indicated for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control. 

The Committee agreed to support the following recommendations on the use of lixisenatide in line with current national (NICE TAGs 203, 248; NICE CG87) and local (JPC Bulletin 164 :-Exenatide twice daily as an adjunctive therapy to basal insulin; JPC recommendation that twice daily exenatide is used as per NICE TA for prolonged release exenatide (TA248)) guidance for the use of exenatide and liraglutide:- |

1 The recommendations have been ratified by BCCG but are interim and awaiting formal ratification by LCCG Clinical Commissioning Committee
The use of lixisenatide in combination with metformin and a sulfonylurea, or metformin and thiazolidinedione, (triple therapy) for adult patients with type 2 diabetes mellitus is supported only if used as described for exenatide in ‘Type 2 diabetes: the management of type 2 diabetes’ (NICE clinical guideline 87); that is, when control of blood glucose remains or becomes inadequate (HbA1c ≥ 7.5%, or other higher level agreed with the individual), and the person has:

- a body mass index (BMI) ≥ 35 kg/m² in those of European descent (with appropriate adjustment for other ethnic groups) and specific psychological or medical problems associated with high body weight, or
- a BMI < 35 kg/m², and therapy with insulin would have significant occupational implications or weight loss would benefit other significant obesity-related comorbidities.

Treatment with Lixisenatide in a triple therapy regimen should only be continued as described for exenatide in ‘Type 2 diabetes: the management of type 2 diabetes’ (NICE clinical guideline 87); that is, if a beneficial metabolic response has been shown (defined as a reduction of at least 1 percentage point in HbA1c and a weight loss of at least 3% of initial body weight at 6 months).

The use of lixisenatide in combination with metformin or a sulfonylurea (dual therapy) for adult patients with type 2 diabetes mellitus only if:

- The person is intolerant of either metformin or a sulfonylurea, or treatment with metformin or a sulfonylurea is contraindicated and
- The person is intolerant of thiazolidinediones and dipeptidyl peptidase-4 (DPP-4) inhibitors, or treatment with thiazolidinediones and DPP-4 inhibitors is contraindicated.

Treatment with lixisenatide in a dual therapy regimen should only be continued if a beneficial metabolic response has been shown (defined as a reduction of at least 1 percentage point in HbA1c at 6 months).

The use of lixisenatide in combination (as an adjunctive therapy) with basal insulin, with or without oral glucose-lowering medicinal products is supported in accordance with the locally agreed initiation and discontinuation criteria for twice daily exenatide use. N.B. The SPC for lixisenatide states that lixisenatide should not be given in combination with basal insulin and a sulfonylurea due to increased risk of hypoglycaemia. Use in this circumstance is therefore not recommended and sits outside of shared care arrangements.

Lixisenatide should be initiated in specialist/tertiary care and prescribing continued by GPs under a shared care arrangement.

Draft shared care guidelines to support the introduction of lixisenatide were considered by the Committee and subject to confirmation of some outstanding information (from the BNF) were agreed.

The JPC agreed to flag the following information relating to GLP-1 medicines to GPs, noting that this is considered to be a class effect associated with these medicines:-

The MHRA had recently (10 June) issued a statement on the use of GLP-1
medicines ([http://www.mhra.gov.uk/NewsCentre/CON286853](http://www.mhra.gov.uk/NewsCentre/CON286853)) in response to the publication of a recent study of incretin-based therapies which highlighted an increased risk of pancreatitis and pre-cancerous cellular changes of the pancreas in patients with type 2 diabetes treated with these medicines. The statement advised the following:

‘Healthcare professionals should continue to prescribe these medicines in line with the product information. There is no need for patients using these medicines to stop taking them. If patients have questions about their diabetes treatment they should consult their GP or pharmacist.

Effects on the pancreas were identified as a possible risk for these medicines during their initial evaluation and rare cases of pancreatitis have been reported. The risk of pancreatitis is already known and warnings are included in the product information for all of these medicines. Your doctor will take this into account when prescribing this medication.

The European Medicines Agency (EMA) ([external link](http://www.mhra.gov.uk/NewsCentre/CON286853)) is currently investigating the information provided by the researchers to determine the need for any change to the way these products are used. The MHRA is providing input to this assessment, which is ongoing; the EMA has not yet reached any conclusions on the investigation.’

| Bedfordshire COPD Guidelines Updated 2013 “Updated Guidelines supported and included with the Newsletter” | The JPC previously agreed the Bedfordshire COPD guidelines in outline and comments were fed back to the Respiratory Implementation Group (RIG) that had drafted the guidelines. Further amendments had been made to the guidelines and these were presented to the JPC for discussion and comment. Changes made included incorporating previously JPC agreed change to second choice LAMA, Spiriva Respimat® and warnings, adding a new treatment pathway for COPD patients with a history of asthma and a slight re-organisation of the document so that it flowed more logically. It was noted that the revised guidelines had gone out for wide consultation and included Bedfordshire and Luton Respiratory Leads who supported the guidelines.

With a number of minor suggested amendments, the guidelines were supported and are enclosed with the mailing.

The Committee also agreed to update the Inhaled Aclidinium bromide and Inhaled Glycopyrronium bromide bulletins to include the wording (re MHRA advice) as outlined on the updated guidelines and reference to use of both within the updated and approved COPD pathway. |
| Shared Care Guidelines for Drugs used in the Treatment of Alzheimer’s Disease - Update “Updated Guidelines agreed in principle. Guidelines to be issued when both CCGs have agreed to commission the new SEPT Memory Assessment Pathway” | This agenda item came to update the Committee on revision of the shared care guidelines for drugs used in the treatment of Alzheimer’s Disease. SEPT had developed a revised Memory Assessment Patient Pathway for the diagnosis and treatment of Alzheimer’s Disease which required an update of the current shared care guideline. The revised pathway has been agreed by LCCG but discussions are still ongoing within BCCG.

With amendments agreed at the meeting, the shared care protocol was approved, however, to avoid confusion, the shared care protocol would not be issued until after BCCG had supported the revised SEPT Memory Assessment Pathway. |
| JPC Annual Report 2012/13 | The JPC Annual Report was approved by the Committee and will shortly be available on GPref. |
The Drug Safety Updates were brought to the Committee for information and noting.

**April 2013 DSU**

**Strontium ranelate (Proteolos®): risk of serious cardiac disorders – restricted indications, new contraindications, and warnings.**

The current JPC Osteoporosis Guidelines for Primary Care (issued Sept 11) support the use of Strontium Ranelate as a 3rd line treatment option (alongside denosumab) in patients (post-menopausal women and men) with osteoporosis who cannot receive generic alendronate 70 mg weekly or generic risedronate 35 mg weekly.

The Committee agreed to update JPC guidance as a result of the DSU as follows:-

- ‘Strontium is currently not recommended as a 3rd line therapy, due to the recent MHRA warning on its cardiac and vascular risks’ ([http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con267913.pdf](http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con267913.pdf)).

It should only be initiated by a physician with experience in the treatment of osteoporosis, and the decision to prescribe Strontium Ranelate should be based on an assessment of the individual patient’s overall risk.’

For existing patients, the MHRA Guidance states that ‘Healthcare Professionals should review patients at a routine appointment and decide whether or not to continue treatment’.

**May 2013 – Drug Safety Update (DSU)**


The JPC recommended (in Dec 09) that tolvaptan should be prescribed by specialists only. In Sept 11, the JPC agreed that it would be appropriate for GPs to take responsibility for monitoring sodium levels after treatment with tolvaptan was completed after discharge (3 months after discharge) and that a shared care guideline was not required.

The Committee agreed that although GPs received the DSU directly, it would be helpful to have the new information on liver function test monitoring reiterated.

### SECONDARY CARE PRESCRIBING/COMMISSIONING ISSUES – all items “Hospital Prescribing Only”

**Tocilizumab (Monotherapy for patients with Rheumatoid Arthritis)**

‘**Indication supported, Consultant only prescribing.**’


The Luton and Dunstable Hospital Rheumatology team presented a Business Case for the use Tocilizumab as a monotherapy treatment option (2nd line to etanercept or adalimumab monotherapy, which are recommended by NICE as monotherapy options) in patients who are intolerant to methotrexate or where continued treatment with methotrexate is inappropriate.

The following recommendation was agreed:-

- To support the use of Tocilizumab as a monotherapy treatment option (2nd line to etanercept or adalimumab monotherapy, which are recommended by NICE as monotherapy options) in adult patients with moderate to severe rheumatoid arthritis who are intolerant to methotrexate (administered orally and by subcutaneous injection*) or where methotrexate is contraindicated.

* Noted that patients who cannot tolerate oral methotrexate are switched to methotrexate administered by subcutaneous injection in order to maximise the use of methotrexate. This option should always be considered prior to moving on to
The JPC noted the following NICE Guidance:

- **Omalizumab** for treating severe persistent allergic asthma (review of technology appraisal guidance 133 and 201), NICE TAG 278, issued April 2013. [http://guidance.nice.org.uk/TA278](http://guidance.nice.org.uk/TA278)
  
  NHSE has commissioning responsibility for omalizumab.

- **Abatacept** for treating rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs (rapid review of technology appraisal guidance 234), NICE TAG 280, issued April 2013. [http://guidance.nice.org.uk/TA280](http://guidance.nice.org.uk/TA280)

- **Canakinumab** for treating gouty arthritis attacks and reducing the frequency of subsequent attacks (terminated appraisal) NICE TAG 281, issued April 2013. [http://guidance.nice.org.uk/TA281](http://guidance.nice.org.uk/TA281)
  
  NHSE has commissioning responsibility for canakinumab.

  
  NHSE has commissioning responsibility for Pirfenidone. The Manufacturer has confirmed that the PAS is not available in Primary Care. It is anticipated that the drug will be prescribed from Specialist Respiratory Centres and supplied via a Homecare arrangement to patients. Hospitals/Specialists are advised to confirm that funding is available via their local area teams prior to prescribing. **No GP Prescribing is recommended.**


  
  Chemotherapy is now a NHSE Commissioning responsibility.

  
  Chemotherapy is now a NHSE Commissioning responsibility.

- **Loxapine inhalation** for treating acute agitation and disturbed behaviours associated with schizophrenia and bipolar disorder (terminated appraisal), NICE TAG 286, issued May 2013. [http://guidance.nice.org.uk/TA286](http://guidance.nice.org.uk/TA286)

  Loxapine has been discussed by SEPT DTC (June 13 meeting) and use was not supported.

**Proposed / Potential June 2013 JPC items**

- Update of shared care guidelines on ADHD treatments to include lisdexamfetamine dimesylate
- Botulinum toxin Policy Update
- Fluticasone furoate plus vilanterol for the treatment of COPD
- Update of Biologicals Pathway
- Drug Monitoring for IBD

If you are interested in commenting on any of these items, please contact [Jacqueline.clayton@bedfordshire.nhs.uk](mailto:Jacqueline.clayton@bedfordshire.nhs.uk).

**Website Access to JPC Documents:**

The JPC papers from the meeting will shortly be available on the GP ref website ([http://www.gpref.bedfordshire.nhs.uk](http://www.gpref.bedfordshire.nhs.uk)). It is necessary to register with the site to obtain full access to all papers (historical documents, pre September 2012 are password protected). If you wish to receive copies of any of the more detailed documents flagged in the Newsletters (prior to information being available on the GPref site), please contact [Jacqueline.clayton@bedfordshire.nhs.uk](mailto:Jacqueline.clayton@bedfordshire.nhs.uk) or [Sandra.McGroarty@bedfordshire.nhs.uk](mailto:Sandra.McGroarty@bedfordshire.nhs.uk).

Comments are always welcome to [Jacqueline.clayton@bedfordshire.nhs.uk](mailto:Jacqueline.clayton@bedfordshire.nhs.uk).