Key updates to the Buckinghamshire Formulary* December 2020

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Green	Updated recommendations regarding medicines for treatment of overactive bladder (OAB)	Licensed

Following a review of OAB medicines in terms of efficacy, safety (including anticholinergic effects on cognition(AEC) and cost, the formulary now recommends the following:

- **1st CHOICE**: Solifenacin 5mg / 10mg tablets or trospium 20mg tablets
- **2nd CHOICE:** Mirabegron MR 50mg tablets if a 1st choice option is ineffective or not tolerated after a 4 to 6 week trial

The traffic light classification of mirabegron has been revised from Amber Recommendation to Green.

The following guidelines have been updated and uploaded to the formulary::

- **110FM Medical management of overactive bladder**
- **114FM Management of urinary incontinence in adult females.**

OAB treatment for paediatric and spinal cord injured patients may vary from those recommended in these guidelines.

Amber recommendation	Updated Gonadorelin analogues (GnRHa): Triptorelin, Goserelin, Leuprorelin for prostate cancer Guideline	Licensed

- The traffic light classification of GnRHa has been revised from Amber Protocol to Amber recommendation.
- This guideline provides prescribing and monitoring guidance for triptorelin, goserelin and leuprorelin use in prostate cancer.
- Triptorelin 22.5 mg (six monthly injection) is the 1st choice GnRHa for treatment of metastatic prostate cancer patients on life-long treatment on the Bucks formulary.
- The guideline includes information on switching patients to triptorelin 22.5mg 6 monthly. This is recommended only for existing metastatic prostate cancer patients already on life-long monthly or 3 monthly goserelin, leuprorelin or triptorelin injections.
- The traffic light classification of flutamide and bicalutamide were revised to become amber recommendation. This allows GPs to coordinate the timing of starting these drugs in advance of the GnRHa (following Specialist advice).
- Note: Funding of GPs for administration of the first choice GnRHa for prostate cancer via a Near Patient Testing fee will continue.
  Please click on the following link to view the full guideline

Amber initiation	Sotagliflozin with insulin for type 1 diabetes (T1D) – NICE TA 622.	Licensed

- Sotagliflozin inhibits both SGLT1 and SGLT2 receptors whilst dapagliflozin only inhibits SGLT2 receptors. Both have the same licensed indication and NICE TA recommendations for T1D.
- Sotagliflozin is licensed for T1D whereas dapagliflozin is licensed for both T1D and T2D.
- Sotagliflozin is more expensive than dapagliflozin.

Sotagliflozin 200mg tablets have been approved for formulary inclusion as follows:

- With insulin for the treatment of type 1 diabetes in accordance with NICE TA 622.
- Initiation and stabilization of treatment by consultant Diabetologists before continuation of prescribing by GPs. Patients receive structured education about management and monitoring for DKA and the use ketone meters. They are regularly followed up by the specialists.

Amber protocol	Denosumab for fracture prevention in women and men over the age of 50	Licensed

In response to the MHRA Drug Safety Update about an increased risk of multiple, vertebral fractures after stopping or delaying ongoing denosumab 60mg (Prolia®), the following is recommended in Bucks:
Do NOT stop or delay denosumab without prior specialist advice. Use 'Advice and Guidance' via ERS:

- at the end of a treatment cycle.
- if there are concerns about serious side effects prior to giving the next injection (mark request as 'urgent').

Produced by the Medicines Resource Centre, Buckinghamshire Integrated Care Partnership
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The Denosumab for fracture prevention shared care protocol has been updated to incorporate these messages

Further local guidance on denosumab is being developed and will be circulated in the next two months.

Amber protocol	NEW electronic shared care agreement (SCA) letter and process	

A NEW shared care agreement (SCA) letter and process have been developed to facilitate electronic communication between the specialist and GP and reduce delays in transfer of care.

What are the main differences?

- Sent and returned electronically
- Sent to the GP **at the point when the patient is stable on treatment** and ready for shared care
- **Sent together with the latest clinic letter which confirms the dose and follow up arrangements**
- **Requires NO patient signature**. This is replaced by the specialist's statement confirming that the patient has received counselling and agrees to book and attend necessary blood test monitoring and contact the GP for the results.
- **Requires NO consultant or GP signature**

The new SCA letter and process are Linked here and

- to all shared care protocols (below 'Back up information and advice'). Shared care protocols are on the Bucks formulary guidelines page http://www.bucksformulary.nhs.uk/docs/sc/
- On DOCgen (currently for DMARDs only. This will be expanded to include all amber protocol drugs).

Red	VTE prevention in patients 16 years and above on wards (except ICU) during COVID-19	Off label

- Due to the pro-thrombotic nature of COVID, BHT has implemented a new guideline on VTE prevention in COVID positive in-patients
- These patients will be discharged on a course of either a weight-based prophylaxis dose of dalteparin or rivaroxaban 10mg tablets. Either treatment will be prescribed and supplied by the hospital for 14 or 30 days depending on the patients VTE risk factors and consideration of their bleeding risk.
- There is no action required from GPs, except to be aware of this current hospital prescribing practice.

Red	Ustekinumab for moderate to severely active ulcerative colitis – NICE TA 633	Licensed

Ustekinumab 130mg / 26mL concentrate for solution for infusion and Ustekinumab 90 mg/mL pre-filled injection have been approved for formulary inclusion as follows:

- For treatment of moderate to severely active ulcerative colitis in accordance with NICE TA 633 and guideline 633FM.3 Biologic and immunomodulatory drugs in ulcerative colitis (updated in process).
- Prescribing by consultant Gastroenterologists.

The updated guideline 633FM.3 Biologic and immunomodulatory drugs in ulcerative colitis will be uploaded.

Red	Fremanezumab for preventing migraine – NICE TA 631	Licensed

- Fremanezumab is a monoclonal antibody which inhibits calcitonin gene-related peptides. Triptans also block this pathway when used for acute management of migraine
- Fremanezumab and Botox® have the same NICE criteria for use.
- Botox® is followed up and re-administered if needed every three months. Fremanezumab is an s/c injection and is also followed up at 3 months to review response. If effective, treatment will continue and the patient will be followed up at 12 months and then annually.
- Patients who fail on Fremanezumab will be offered Botox® and vice versa.

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Fremanezumab (Ajovy®) 225mg/1.5ml solution for injection, pre-filled syringe have been approved as follows:

- For prophylaxis of migraine in accordance with NICE TA 613
- Prescribe by brand name.
- Prescribing by consultant Neurologists.

Red	**Patiromer for treating hyperkalaemia – NICE TA 623**	Licensed

Patiromer 8.4g and 16.8g oral powder sachets have been approved for formulary inclusion as follows:

- For treatment of hyperkalaemia in accordance with NICE TA 623

Sodium zirconium cyclosilicate for hyperkalaemia, (NICE TA 599) was added to the formulary in December 2019. Work to produce / update guidelines regarding the use of these drugs in the management of acute and chronic hyperkalaemia is planned.

Red	**Oncology and Haematology NICE TAs**	Licensed

The following have been approved for formulary inclusion:

Prescribing by the Haematology team

- Avatrombopag for thrombocytopenia in people with chronic liver disease needing a planned invasive procedure in accordance with NICE TA 626, Jun 20, BNF code 09.01.04, no PAS, PbRe CCG
- Lenalidomide with rituximab for previously treated follicular lymphoma in accordance with NICE TA 627, April 20, BNF code 08.02.04
- Obinutuzumab with bendamustine for follicular lymphoma after rituximab in accordance with NICE TA 629, May 2020, BNF code 08.02.03

Prescribing by the Oncology team

- Lorlatinib for previously treated ALK-positive advanced non-small-cell lung cancer in accordance with NICE TA 628, BNF code 08.01.05 Protein kinase inhibitors
- Larotrectinib for NTRK fusion-positive solid tumours, NICE TA 630, May 2020 BNF code 08.01.05 Protein kinase inhibitors
- Trastuzumab emtansine for adjuvant treatment of HER2-positive early breast cancer in accordance with NICE TA 632, May 2020 BNF code 08.01.05 Trastuzumab
- Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer NICE TA 638, July 2020. BNF code 08.01.05 other antineoplastic drugs
- Atezolizumab with nab-paclitaxel for untreated PD-L1-positive, locally advanced or metastatic, triple-negative breast cancer, NICE TA 639, July 2020. BNF code 08.01.05 other antineoplastic drugs

ABBREVIATIONS

DOAC: Direct –acting oral anticoagulant:
OAB: Overactive bladder

Any queries about the above, please contact the Bucks Medicines Resource Centre
By email bucks.medicinesresourcecentre@nhs.net . Urgent queries: by phone, weekdays 9am to 5pm: 01494 425355

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