AREA PRESCRIBING COMMITEE NEWSLETTER

10TH May 2018

**1)Formulary Amendments and Additions   
2)NICE Technical Appraisals  
3)Items approved at Area Prescribing Committee  
4)MHRA Alerts   
5)Net Formulary update**

**1) Formulary Amendments and Additions**

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| **Name of Drug** | **RAG Rated** | **Information** |
| **Freestyle Libre** | **Red** | NICE have released a Medtech innovation briefing [MIB110] regarding Free style Libre which was published in July 2017, Further information can obtained via the NICE website <https://www.nice.org.uk/advice/mib110>  The Regional Medicines Optimisation Committee ( north) have also issued a position statement regarding freestyle libre which can viewed via <https://www.sps.nhs.uk/wp-content/uploads/2017/11/Flash-Glucose-monitoring-System-RMOC-Statement-final-2.pdf>  In view of the above statements the Northern Lincolnshire Area Prescribing Committee( APC) have issued the following positioning statement for free style libre;  ‘*The APC have adopted the RMOC statement and it has been agreed that this would be provided by the Acute Trust’ and not to be issued by Primary Care’* |
| **Sumatriptan injections for cluster headaches** | **Amber** | Sumatriptan Injection have been agreed to be included this onto the formulary as Amber (specialist initiation) for cluster headaches. |
| **Tinzaparin subcutaneous injection** | **RED** | It has been agreed for tinzaparin to remain as RED (hospital only) until the low molecular weight guidelines have been approved and ratified. It has been noted that in some cases Primary care prescribers/ General practitioners can use their clinical discretion to prescribe if warranted. |
| **Tadalafil once daily** | **Red** | Tadalafil once daily preparation has been amended from GREEN to RED (hospital only) prescribing with restrictions following the items for review document. Further evidence is to be requested to stipulate the clinical indications to sustain its position and use on the formulary. |
| **Midodrine** | **RED** | It is unclear from the licencing as to how this would be RAG rated without shared care being in place. It was agreed that it would be RAG rated RED ( Hospital Only) until a shared care protocol or agreement is in place. |
| **Dulaglutide**  **(Trulicity)** | **Amber** | Dulaglutide was agreed to be included onto the formulary in February and listed as Amber ‘specialist only’. It have been discussed further and the decision has been made for Trulicity to remain Amber but to include the following phrase from the diabetes pathway ‘Initiation of GLP1 analogues to be carried out by only prescribers trained in insulin therapy’ this will enable prescribers sufficiently trained to prescribe it, and avoid unnecessary restrictions. |

**2)NICE Technical Appraisals**

March and April 2018 Technical Appraisals

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| **NICE TA** | **indication** | **RAG rating** |
| NICE TA504 | Pirfenidone for treating idiopathic pulmonary fibrosis | RED |
| NICE [TA505](https://www.nice.org.uk/guidance/ta505) | Ixazomib with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma. | RED |
| NICE [TA507](https://www.nice.org.uk/guidance/ta507): | Sofosbuvir–velpatasvir–voxilaprevir for treating chronic hepatitis C. | RED |
| NICE [TA511](https://www.nice.org.uk/guidance/ta511) | Brodalumab for treating moderate to severe plaque psoriasis | RED |
| NICE [TA512](https://www.nice.org.uk/guidance/ta512) | Tivozanib for treating advanced renal cell carcinoma | RED |
| NICE [TA509](https://www.nice.org.uk/guidance/ta509) | Pertuzumab with trastuzumab and docetaxel for treating HER2-positive breast cancer. | RED |
| NICE [TA510](https://www.nice.org.uk/guidance/ta510) | Daratumumab monotherapy for treating relapsed and refractory multiple myeloma. | RED |
| NICE [TA513](https://www.nice.org.uk/guidance/ta513) | Obinutuzumab for untreated advanced follicular lymphoma | RED |
| NICE [TA516](https://www.nice.org.uk/guidance/ta516) | Cabozantinib for treating medullary thyroid cancer. | RED |

Highly Specialised Technology Appraisal   
[HST7](https://www.nice.org.uk/guidance/hst7): Strimvelis for treating adenosine deaminase deficiency–severe combined immunodeficiency .RAG Rating :RED (Hospital only)

**3) Items Approved at APC**

* Patient referral Information leaflet



* Policy for the introduction, management and use of Biosimilar medicinal products



* Pain & Symptom Management Guidance in the last days of life  
  <http://www.northernlincolnshireapc.nhs.uk/wp-content/uploads/2018/06/Pain-and-Symptom-Management-Guidance-in-the-Last-Days-of-Life-DCM029-1.pdf>

**4)MHRA Alerts**

March & April MHRA Alerts

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| **Date** | **Product** | **Problem** | **Advice** |
| [**https://www.gov.uk/government/publications/drug-safety-update-monthly-newsletter**](https://www.gov.uk/government/publications/drug-safety-update-monthly-newsletter) | | | |
| 09/03/2018 | **Daclizumab (Zinbryta▼)** | Suspension and recall for safety reasons; review patients as soon as possible and start alternative therapy | **Advice for healthcare professionals**: • Following the initiation of an urgent safety review, the European Medicines Agency (EMA) recommend that: o patients should not be started on daclizumab o doctors should contact all patients receiving daclizumab as soon as possible and stop their treatment. Alternative therapy should be considered in line with national recommendations (eg, NICE guidance) o doctors should monitor all patients stopping daclizumab for adverse reactions and check their liver function tests at least monthly and more frequently if clinically indicated for up to 6 months after the last dose o doctors should advise patients to seek urgent medical attention if they develop severe headache or any symptoms of liver injury such as prolonged fever, abdominal pain, jaundice, dark urine, or unexplained nausea or vomiting; serious immune-mediated hepatic injury can occur up to 6 months after the final dose. o patients should talk to their doctor if they have any questions about daclizumab • The EMA’s recommendation to suspend Zinbryta and recall the product is being sent to the European Commission for a legally binding decision |
| 09/03/2018 | **Esmya (ulipristal acetate) for uterine fibroids** | Do not initiate or re-start treatment; monitor liver function in current and recent users | **Advice for healthcare professionals:** • do not initiate new treatment courses of Esmya, including in women who have completed one or more treatment courses previously • perform liver function tests at least once a month in all women currently taking Esmya and again 2–4 weeks after stopping treatment. • check transaminase levels immediately in current or recent users of Esmya who present with signs or symptoms suggestive of liver injury (for example, nausea, vomiting, malaise, right hypochondrial pain, anorexia, asthenia, or jaundice) • stop Esmya in any woman who develops transaminase levels more than 2-times the upper limit of normal, closely monitor and refer women for specialist hepatology evaluation as clinically indicated • advise women using Esmya about the signs and symptoms of liver injury and tell them to seek immediate medical attention if they occur |
| [**https://www.gov.uk/government/publications/drug-safety-update-monthly-newsletter**](https://www.gov.uk/government/publications/drug-safety-update-monthly-newsletter) | | | |
| 24/04/2018 | **Valproate medicines (Epilim▼, Depakote▼):** | Contraindicated in women and girls of childbearing potential unless conditions of Pregnancy Prevention Programme are met | **Advice for healthcare professionals: •** valproate medicines must not be used in women and girls of childbearing potential unless the conditions of the Pregnancy Prevention Programme are met (see below) and only if other treatments are ineffective or not tolerated, as judged by an experienced specialist • you will receive materials by post in the coming weeks to use in the implementation of the Pregnancy Prevention Programme (Patient Guide, Healthcare Professional Guide, Risk Acknowledgement Form, and, for pharmacists, Patient Cards and stickers to attach a warning label to the pack) • GPs must identify and recall all women and girls who may be of childbearing potential, provide the Patient Guide and check they have been reviewed by a specialist in the last year and are on highly effective contraception (see later for information on contraception) • specialists must book in review appointments at least annually with women and girls under the Pregnancy Prevention Programme and re-evaluate treatment as necessary; explain clearly the conditions as outlined in the supporting materials; and complete and sign the Risk Acknowledgement Form—copies of the form must be given to the patient or patient/caregiver/responsible person and sent to their GP **Contraindication in pregnancy** • use of valproate medicines in pregnancy is contraindicated for bipolar disorder and must only be considered for epilepsy if there is no suitable alternative treatment |
| 24/04/2018 | **Obeticholic acid (Ocaliva▼):** | Risk of serious liver injury in patients with pre-existing moderate or severe hepatic impairment; reminder to adjust dosing according to liver function monitoring | **Advice for healthcare professionals:** • patients with pre-existing moderate or severe liver impairment who are taking obeticholic acid are at risk of serious liver injury; adequate dose reduction in these patients is therefore essential • assess hepatic status before starting obeticholic acid • start patients with Child-Pugh Class B or C or decompensated liver cirrhosis at a reduced dose of 5 mg once a week (rather than once a day) and only increase dosing frequency to 5 mg twice a week (at least 3 days apart) and subsequently 10 mg twice a week (at least 3 days apart) in these patients if an adequate reduction in alkaline phosphatase and/or total bilirubin has not been achieved after 3 months and if the patient is tolerating the medicine – see Summary of Product Characteristics • monitor all patients for primary biliary cholangitis (PBC) progression with laboratory and clinical assessment and evaluate at regular intervals the need for dose r**eduction** |

**5) Net Formulary update**We are continuing to update our joint formulary available at: <http://www.northernlincolnshireapc.nhs.uk/formulary-documents/formulary/chapter-2/>

Net Formulary holds information about drugs and their formulary status. It also includes traffic light status of medications so that prescriber responsibilities are clear. Pathways, NICE and APC policies will be linked to this as well as APC minutes and policies. This is an active document which is being continually updated. Please feel free to provide feedback or comments to the Area Prescribing Professional secretary Aliya Turk at [aliya.turk@nhs.net](mailto:aliya.turk@nhs.net)