APC Newsletter

Northern Lincolnshire
Area Prescribing Committee
>>*May 2016*

Newly Available Treatments

On 14th April, the APC convened to review several treatments. The treatments and outcomes are below:

AirFluSal has been added to the Formulary for use in COPD. AirFluSal (DPI with fluticasone propionate 500mcg and salmeterol 50mcg) can be considered as an alternative for patients stabilised on Seretide Accuhaler 500. This drug combination/strength is not recommended for new initiation, except in a specialist setting. However, a switch may be made following appropriate patient counselling. The AirFluSal Dry Powder Inhaler can be found in Formulary Chapter 3.2.

Idarucizumab Injection has been added to the Formulary for use in secondary care and specialist regional centres only. This is the first available reversal agent for a NOAC. In due course there may be an agent available to reverse the anti Xa inhibitors, but so far only idarucizumab specifically for the direct thrombin inhibitor dabigatran is available. An 'all' NOAC reversal agent is unlikely because dabigatran works on a different part of the clotting cascade system to the other NOACs. Idarucizumab (brand name Praxbind) can be found in Formulary Chapter 2.8.4.

Insulin Degludec, brand name **Tresiba** has been added to the Formulary. This should only be initiated by a specialist. Tresiba may offer effective glycaemic control in type 1 and type 2 diabetic patients with high HbA1c, hyper-variable glycaemia or limiting hypoglycaemia despite trials of all other available preparations (please see local Type 2 Diabetes Pathway). Tresiba (based on current information and evidence) may be a suitable step prior to considering insulin pump therapy. Tresiba can be found in Formulary Chapter 6.1.1.2.

Insulin Degludec with Liraglutide, brand name **Xultophy** has been added to the Formulary strictly for specialist initiation only. The Xultophy pen delivers insulin degludec in 1 unit per dose-step and liraglutide 36 micrograms per dose-step. Xultophy has a net price of £159.22 per 5 x 3mL prefilled pens. Counselling is essential upon initiation; the prescriber should ensure that the patient understands the dosing structure and method of administration. Xultophy can be found in Formulary Chapter 6.1.2.3.

NICE TA375 was discussed and approved for local use. In summary:

Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis.

This is only if the disease is severe, that is, a disease activity score (DAS28) greater than 5.1, the disease has not responded to intensive therapy with a combination of conventional disease-modifying anti-rheumatic drugs (DMARDs) and the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their patient access schemes.

Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria above are met.

Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained.

Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules.

People whose treatment with adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab or abatacept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published should be able to continue treatment until they and their NHS clinician consider it appropriate to stop. These medicines are all specialist, secondary care only medicines. NICE TA375 can be viewed here.

Radium-223 Dichloride is recommended as an option for treating adults with hormone-relapsed prostate cancer, symptomatic bone metastases and no known visceral metastases, only if the patient has had treatment with docetaxel and the company provides radium-223 dichloride with the discount agreed in the patient access scheme. Radium-223 dichloride has received a positive NICE Technology Appraisal (NICE TA376). The APC agreed that use as per TA376 is in accordance with regional needs and radium-223 dichloride has been added to Formulary Chapter 8.3.

Enzalutamide Tablets have received a positive NICE Technology Appraisal (NICE TA377). The APC agreed that use as per TA377 is in accordance with regional needs and enzalutamide tablets have been amended in Formulary Chapter 8.3.4.2.

NICE TA378 (ramucirumab alone or with paclitaxel is not recommended within its marketing authorisation for advanced gastric cancer or gastro–oesophageal junction adenocarcinoma previously treated with chemotherapy) is not recommended.

Please refer to the APC Formulary and relevant pathways for further information:

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Nintedanib Capsules have received a positive NICE Technology Appraisal (NICE TA379). The APC agreed that use as per TA379 is in accordance with regional needs and this has been amended in Formulary Chapter 8.1.5.

Panobinostat in combination with bortezomib and dexamethasone has received a positive NICE Technology Appraisal (NICE TA380). The APC agreed that use as per TA380 is in accordance with regional needs and Panobinostat has been added to Formulary Chapter 8.1.5.

Olaparib Capsules have received a positive NICE Technology Appraisal (NICE TA381). The APC agreed that use as per TA381 is in accordance with regional needs and this has been amended in Formulary Chapter 8.1.5.

NICE TA382 (eltrombopag for treating severe aplastic anaemia refractory to immunosuppressive therapy) is not recommended.

Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab have received a positive NICE Technology Appraisal (NICE TA383). The APC agreed that use as per TA383 is in accordance with regional needs and a link to TA383 has been added to the Formulary.

Nivolumab Injection has received a positive NICE Technology Appraisal (NICE TA384). The APC agreed that use as per TA384 is in accordance with regional needs and this has been added to Formulary Chapter 8.2.3.

NICE TA385 has been published and replaces TA132. This relates to cardiovascular disease. This guidance should be used with all NICE guidelines for cardiovascular disease i.e. risk assessment and reduction, including lipid modification and familial hypercholesterolaemia. Within this guidance, ezetimibe monotherapy is recommended as an option for treating primary (heterozygous-familial or non-familial) hypercholesterolaemia in adults in whom initial statin therapy is contraindicated and as an option for treating primary (heterozygous-familial or non-familial) hypercholesterolaemia in adults who cannot tolerate statin therapy. Also, ezetimibe, co-administered with initial statin therapy, is recommended as an option for treating primary (heterozygous-familial or non-familial) hypercholesterolaemia in adults who have started statin therapy when, serum total or low-density lipoprotein (LDL) cholesterol concentration is not appropriately controlled either after appropriate dose titration of initial statin therapy, or because dose titration is limited by intolerance to the initial statin therapy and a change from initial statin therapy to an alternative statin is being considered. For the purposes of TA385, intolerance to initial statin therapy is defined as the presence of clinically significant adverse effects that represent an unacceptable risk to the patient or that may reduce compliance with therapy. The full details can be viewed here.

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