Item Number: 12

NHS VALE OF YORK CLINICAL COMMISSIONING GROUP **GOVERNING BODY MEETING**	NHS Vale of York Clinical Commissioning Group

Meeting Date: 4 April 2013

Report Sponsor:	**Report Author:**
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1. Title of Paper: Adoption of Treatment Advisory Group Recommendations from September 2012, November 2012, January 2013 and February 2013

2. Strategic Objectives supported by this paper

1. Improve healthcare outcomes
2. Reduce health inequalities
3. Improve the quality and safety of commissioned services
4. Improve efficiency

3. **Executive Summary**

The Treatment Advisory Group reviews the evidence for new treatments that have not, to date been provided within our area.

4. Evidence Base

The terms of reference for the Treatment Advisory Group are attached. The group consists of representatives of members of the Commissioning Support Unit's Medicine's Management Pharmacists, primary and secondary care clinicians who work on behalf of the North Yorkshire and Humber Clinical Commissioning Groups.

5. Risks relating to proposals in this paper

If the CCG does not adopt the recommendations of the TAG, without good reason, it will limit the treatment choices of the patients it serves and this risks potentially worse quality care.

6. Summary of any finance / resource implications

It is expected that any increase in costs will be managed within existing resources. Some of the recommendations are expected to generate cost efficiencies over existing medicines

7. Any statutory / regulatory / legal / NHS Constitution implications

Any drugs that NICE have recommended commissioners are obliged to ensure are available where clinicians feel they are indicated.

8. Equality Impact Assessment

Not applicable

9. Any related work with stakeholders or communications plan

The North Yorkshire CCGs share their recommendations with each other to ensure as much uniformity across North Yorkshire as possible.

The CCG will share the recommendations with the local Drugs and Therapeutics Committee (a joint commissioner and provider committee with York Hospital NHS Foundation Trust). This committee will confirm the addition of recommended drugs to the local Formulary and after which communications to primary and secondary care clinicians follow.

10. Recommendations / Action Required

The Governing Body is asked to approve the recommendations.

11. Assurance

The CCG Prescribing Lead and Medicine Management colleagues from the CSU will communicate the decisions to local General Practitioners and Secondary Care colleagues and discuss pathways, where needed for the implementation of these new options in treatment.

NHS VALE OF YORK CLINICAL COMMISSIONING GROUP

Governing Body Meeting: 4 April 2013

Adoption of Treatment Advisory Group Recommendations from September 2012, November 2012, January 2013 and February 2013

1. Background

1.1 The Governing Body is asked to approve the recommendations it has received from the Treatment Advisory Group (TAG). The TAG recommends healthcare interventions to Clinical Commissioning Groups based on clinical outcomes, value for money and affordability. Healthcare interventions include drugs, devices, interventional procedures and healthcare programmes.

1.2 The Treatment Advisory Group's Terms of Reference are attached in Appendix 1

1.3 The CCG has received recommendations from TAG following it's meetings in September and November 2012 and January and February 2013. These are attached in appendix 2.

2. Recommendations

The Governing Body is asked to approve the recommendations.

Appendix 1

North Yorkshire and Humber Commissioning Support Unit

Treatment Advisory Group – Terms of Reference

1. Purpose

- To recommend healthcare interventions to Clinical Commissioning Groups based on clinical outcomes, value for money and affordability. Healthcare interventions include drugs, devices, interventional procedures and healthcare programmes

- To assist the Clinical Commissioning Groups in the development of care pathways supported by general commissioning policies and established commissioning arrangements with providers for those treatments which are commissioned

- To assist with consideration of the decommissioning of healthcare interventions as appropriate

- To support the review of commissioning arrangements, as appropriate, after receiving outcome/audit data and financial reports regarding expenditure

- To work with Clinical Commissioning Groups, provider trusts and clinical networks to reduce health inequalities across all localities of interest and responsibility

- To receive Initial Impact Assessments (including red flags, urgent actions, items of interest etc) and Reports/Action Notes from the CSU Impact Assessment Group with a view to issuing Formal Impact Assessments and Policy Recommendations to CCGs .

2. Membership

CSU Commissioning Specialist and Service Delivery lead (Chair)
Public Health Representative(s) as appropriate
Clinical Commissioning Groups representative(s) x 8 or collaborate representative(s)
CSU Management representative
CSU Legal Services manager
CSU Clinical Governance manager
CSU Clinical Triage and Audit Lead
CSU Senior Pharmacists
CSU Commissioning Policy manager
Pharmacy representatives from Clinical Networks

Patient representative (to be advised by CCGs)
Clinical and/or pharmacy representatives from provider trusts, including:

- Hull and East Yorkshire Hospitals NHS Trust
- Northern Lincolnshire and Goole Hospitals NHS Foundation Trust
- York Teaching Hospital NHS Foundation
- South Tees Hospitals NHS Foundation Trust
- Harrogate and District NHS Foundation Trust
- Airedale NHS Foundation Trust
- The Leeds Teaching Hospitals NHS Trust

3. Quoracy arrangements

Commissioner representation of the CCGs (number to be determined), plus one CSU pharmacist and one CSU manager/representative, and a representative from a provider trust

4. Reporting Arrangements

A report will be developed to be shared with Clinical Commissioning Groups/boards (as individually required) as follows and according to individual requirements:

East Riding CCG	Service Redesign & Comm Group
Hull CCG	Area Prescribing Committee
North Lincolnshire CCG	CCG formal Boards/Groups
North East Lincolnshire CCG	
Vale of York CCG	
Hambleton, Richmondshire & Whitby CCG	
Scarborough and Ryedale CCG	
Harrogate and Rural District CCG	

Appendix 2

Vale of York Commissioning Decisions following Policy recommendations from Medicines & Technologies Board (forerunner of TAG)17 September 2012

	Medicines & Technologies Board Recommendation	**Vale of York CCG decision**
1.	**Treatment - Zostavax vaccine** for the prevention of herpes zoster and herpes zoster related post herpetic neuralgia. **Commissioning Recommendation -** Zostavax is **not routinely commissioned** for this indication until the national vaccination campaign is rolled out in September 2013. **Background:** JCVI have recommended to the DoH a national vaccination campaign in patients between the ages of 70-79 years but the manufacturer are unlikely to provide sufficient vaccine until September 2013 to support a national campaign.	**Adopt Recommendation**
2.	**Treatment - Dapoxetine tablets (Priligy)** for the treatment of premature ejaculation **Commissioning Recommendation - Dapoxetine is not routinely commissioned** due to limited evidence base, unknown long term safety outcomes and unknown UK price. **Background:** The MHRA has granted licensing authorisation for dapoxetine for this indication but at present there is no licensed product available in the UK. The manufacturer may launch Priligy in the UK next year. Evidence shows that it is more effective than placebo but only prolongs time from penetration to ejaculation by 1 and 2 minutes.	**Adopt Recommendation**
3.	**Treatment - Ulipristal acetate tablets** for the pre-operative treatment of severe symptoms of uterine fibroids in adult women of reproductive age **Commissioning Recommendation -** The Medicines Technology Board requests that CCGs consider the issues below and assess whether they wish to commission this treatment or not.	**Further work needed to make decision.** **At present, not commissioned.**

	Background: This is the first licensed oral product for this indication, the alterative being GnRH agonist injections e.g. goserelin which are used at present for 3 months prior to surgery. The perceived benefit of this product include oral tablet compared to an injection and its administration, however, concerns were raised regarding patient compliance, administration of an injection would confirm 100% compliance. Patients are likely to develop more side effects with the GnRH agonists compared to ulipristal. None of the clinical trials assessed surgical outcomes following ulipristal treatment. Cost comparison for a 3 month course of ulipristal £342.39 or goserelin £195 (note this does not include administration costs for goserelin which is anticipated to occur in primary care).	
4.	**Treatment – Triptorelin injection (GnRH agonist)** indication under consideration, prostate cancer **Commissioning Recommendation –** Board minded not to position routinely commissioned – CCGs to consider the points below **Background:** Concerns were raised regarding the availability of multiple formulations including Savacyl (triptorelin pamoate) which is only indicated to decrease sexual drive in adult men with severe sexual deviations. In light of this, the case for commissioning above/in addition to goserelin has been raised. Any decision needs to consider within its licensed indications, evidence, adverse effects profile, administration schedule and economic considerations subject to robust agreed shared care guidelines	**Further work needed to make decision.** **At present, not commissioned.**
5.	**Treatment – Dabigatran/rivaroxaban** for prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation as per marketing authorisation **Commissioning Recommendation – Routinely commissioned** as an option incorporating West Yorkshire Cardiovascular Network recommendations	**Adopt Recommendation**

	Background: Dabigatran or rivaroxaban is routinely commissioned as an alternative to warfarin in accordance with NICE TA 249 and TA 256. Further recommendations agreed across the West Yorkshire Cardiac and Stroke Network include: • Warfarin remains first line treatment option • Dabigatran or rivaroxaban is an alternative treatment option for - Those currently taking warfarin with poor INR control (defined as Time in Therapeutic Range <65%), see guidance if TTR not available. - Those with significant problems associated with the monitoring or taking of warfarin (either actual in those taking warfarin or likely in those considered for warfarin). - Those who clearly express the desire not to take warfarin following an informed discussion of the clinical risks and benefits of each agent.	

Vale of York Commissioning Decisions following Policy recommendations from Treatment Advisory Group 12 November 2012 and 7 January 2013

	Treatment Advisory Group Recommendation	Vale of York CCG decision
1.	**Ivabradine – Chronic heart failure** Recommendation: **Ivabradine is recommended as an option for treating chronic heart failure, that is for people:** • with New York Heart Association (NYHA) class II to IV stable chronic heart failure with systolic dysfunction **and** • who are in sinus rhythm with a heart rate of 75 beats per minute (bpm) or more **and** • who are given ivabradine in combination with standard therapy including beta-blocker therapy, ACE inhibitors and aldosterone antagonists, or when beta-blocker therapy is contraindicated or not tolerated and • with a left ventricular ejection of 35% or less. **Key points which were discussed include:** The above recommendation is that of draft NICE due to publish shortly. Ensuring that patients on beta blockers were titrated to target doses were possible given the mortality benefit. Patients receiving 50% or more of target beta-blocker doses at baseline in the trial data had no significant benefit from ivabradine for the primary endpoint which was hospital admission and cardiac death. It was noted that ivabradine offered a reduction in hospitalisation for worsening heart failure, it did not confer mortality benefit. Actual costs are greater than B blockers and/or spironolactone.	**Adopt Recommendation**
2.	**Omalizumab for chronic urticaria** Recommendation: **Omalizumab is not routinely commissioned** for the management of chronic urticaria due to the limited evidence of clinical and absence of cost effectiveness for this indication. **Key points discussed:** The policy was driven by a number of individual funding requests submitted from provider trusts,	**Adopt Recommendation**

	overall funding has not been supported due to the lack of good quality clinical evidence. It has been identified that there are a cohort of patients with whom specialist would like to have access to this treatment which represents a service development for this area. The treatment is not licensed for the proposed indication.	
3.	**Flutiform metered dose inhaler (fluticasone and formoterol) for asthma** Recommendation: **Flutiform is routinely commissioned as a treatment option when an inhaled corticosteroid and long acting B agonist is indicated in the management of asthma** **Key points discussed:** Flutiform has demonstrated non inferiority (not better, not worse) in clinical trials compared with fluticasone and salmeterol i.e. Seretide Other combination inhalers for asthma are available however it is recognised that cost savings may be achieved from use of Flutiform rather than Seretide. Absolute savings cannot be identified from prescribing data as clinical indication (COPD versus asthma) and age cannot readily be removed from the data. It was indicated that CCGs may wish to consider how this treatment will be incorporated in to local asthma guidelines as it was raised there are many different devices and rationalising choices for prescribers/practice nurses may be prudent.	**Adopt Recommendation**
4.	**Omacor in the adjuvant treatment in secondary prevention after myocardial infarction, in addition to other standard therapy.** Recommendation: Omacor is no longer recommended for the treatment in secondary prevention after myocardial infarction. New evidence from a recently published meta-analysis showed it was **not** associated with a lower risk of all-cause mortality, cardiac death, sudden death, MI or stroke. CCGs to consider for existing patients already on Omacor should either be allowed to continue until the next review when the clinician should discuss with the patient about stopping this treatment or whether to advise practices to stop all patients immediately.	**Adopt Recommendation**

	Key points which were discussed include: Present NICE guidance (CG 48; May 2007) advise patients to consume at least 7g of omega 3 fatty acids per week which equates to 2-4 portions of oily fish . Consider prescribing 1g daily of omega -3 acid ethyl esters treatment for up to 4 years in patients unable to achieve this through diet alone. The evidence for this guidance came from the GISSI-Prevenzione trial (Lancet 1999), it was noted that this trial was based in Italy and all most patients were consuming a Mediterranean diet. During this trial the use of secondary prevention treatments were much lower as what would be expected today, this confounding factor was not considered when doing the results. The recent meta-analysis (Rizos et al; JAMA 2012) included 20 clinical trials and data for over 60,000 patients suggested that omega-3 supplementation was not associated with a lower risk of all-cause mortality, cardiac death, sudden death MI or stroke. This study was reviewed in the Drug and therapeutics bulletin (November 2012) who recommended reviewing its place in care pathways and that prescribers discuss the option of discontinuing treatment with patients at the next review. A further retrospective matched-cohort study using the general practice research database published last month (Poole et al; Clinical Therapeutics, December 2012) was also considered. 2466 of subjects exposed to omacor were matched to 9712 subjects not taking omacor, all patients were taking following first MI. It was noted that patients in the omacor group were more likely to be taking other treatments associated with secondary prevention such as lipid lowering therapies, antihypertensives and antiplatelets. The study showed that the group taking omacor was associated with a reduction in risk of all-cause mortality of 21.8%, independent of other cardiovascular risk modifying treatments.	

2.	**Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent DVT and PE following an acute DVT in adults.** Previously approved policy by NHS North Yorkshire and York: • Warfarin/ Low molecular weight heparin remains the treatment of choice for the management of DVT. Patients considered for long term anti-coagulation should be with warfarin as first line treatment option. • Rivaroxaban is an option for the treatment of DVT in patients intolerant/ allergic to warfarin or patients with poor venous access which makes INR monitoring difficult. • Rivaroxaban is an option for long term anti-coagulation in patients unable to be stabilised on warfarin therapy which can be assessed by: ➢ Time in Therapeutic Range (TTR) **less than 60%** based on 6 months of treatment with good concordance. Note: TTR figures are available from some laboratories or practice computer software with INR results. ➢ Where TTR is not available, INR in Range (INRR) less than 50% based on 6 months of treatment with good concordance is a suitable alternative. ➢ OR allergic/ intolerant to warfarin Vale of York CCG have recently changed the contract for INR monitoring from a block contract to case by case. The proposal put forward by York Foundation Hospital Trust was to extend the criteria for use of rivaroxaban to include as a treatment option for DVT caused by transient reversible risk factors eg recent surgery, trauma or immobilisation. Treatment for these patients is routinely 3 months only. Cost of rivaroxaban for 3 months is £235 compared to warfarin which is £343 (includes cost of INR tests). When the treatment course is extended beyond 6 months then rivaroxaban becomes more expensive compared to warfarin. It was highlighted	**Adopt Recommendation**

	that patients managed solely on low molecular weight heparins then rivaroxaban would be also a cost effective option in these patients. Recommendation: Rivaroxaban is recommended to be used as treatment option for patients with provoked DVTs in addition to the above criteria.	
3.	**Aclidinium bromide inhaler for the management of COPD** Recommendation: Await views from acute trust respiratory physicians. Consider at next TAG meeting **Key points which were discussed include:** Aclidinium is a new LAMA for the maintenance treatment of COPD which will compete with tiotropium and glycopyronium. SMC have supported the use as a treatment option. Clinical trials have shown this drug to be more effective than placebo but it was noted that the duration of the trials was relatively short (12 and 24 weeks), so it was not possible to evaluate long term benefits in the management of a chronic condition. At present there are no head to head trials with tiotropium. It is administered via a new inhaler device (Genuair) which is likely to be an alternative option in patients unable to manage the tiotropium spinhaler. The cost is cheaper than tiotropium but slightly more expensive than glyccopyronium. Tiotropium patent expires in 2015. Likely place in therapy would be second line in patients unable to manage the tiotropium spinhaler.	**See February decisions**
4.	**Glyccopyronium bromide breezhaler for the management of COPD** Recommendation: Await views from acute trust respiratory physicians. Consider at next TAG meeting. **Key points which were discussed include:** Glyccopyronium is a new LAMA for the maintenance treatment of COPD which will compete with tiotropium and aclidinium. Evidence from 2 phase III placebo-control studies (GLOW I; 26 weeks and GLOW 2; 52 weeks)	**See February decisions**

	showed a statistically significant improvement in the disease orientated primary end point, 12 week trough FEV1 with glyccopyrronium compared with placebo. GLOW 2 included an open label comparison with tiotropium. Tiotropium was shown to be more effective than placebo and showed similar results to glyccopyrronium. More robust evidence comparing patient-orientated outcomes for glyccopyrronium bromide with other active treatments for COPD would enable its place in therapy to be more clearly established. Glyccopyronium breezhaler device is a single-dosed capsule device with visual and auditory feedback but otherwise very similar to the tiotropium spinhaler. The cost is cheaper than both tiotropium and aclidinium but it was noted that the patent for Spiriva expires in 2015.	

Vale of York Commissioning Decisions following Policy recommendations from February 2013

1.	**Aclidinium bromide inhaler for the management of COPD** Recommendation: Aclidinium bromide inhaler is recommended as second line treatment choice for the management of COPD, in patients unable to manage the tiotropium spinhaler or cannot tolerate tiotropium.	**Adopt Recommendation**
2.	**Glyccopyronium bromide breezhaler for the management of COPD** Recommendation: Glycopyronium bromide breezhaler is not recommended for the treatment of COPD. Evidence showed it to be no more effective than standard treatment and the device did not provide any advantage over the tiotropium spinhaler. The cost at present would provide potential savings in the short term but it was noted tiotropium comes off patent in 2015.	**Adopt Recommendation**
3.	**Racecadotril for the management of acute diarrhoea in infants and children.** Racecadotril is not recommended for the treatment of acute diarrhoea. There is a lack of evidence to show that this treatment will reduce hospital admissions or reduce hospital stay or improve recovery rate.	**Adopt Recommendation**
4.	**Femoro-acetabular arthroscopic surgery (hip arthroscopy)** The CSU does not currently recommend commissioning hip arthroscopy on a routine basis other than where patients are shown to fulfil criteria.	**Adopt Recommendation**