Item Number: 14

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

Meeting Date: 6 June 2013

Report Sponsor:	**Report Author:**
Dr Shaun O'Connell	Dr Shaun O'Connell

1. **Title of Paper: Adoption of Treatment Advisory Group Recommendations from April 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 (TAG) reviews the evidence for new treatments that have not, to date been provided within our area. The Terms of Reference of this group were circulated to the Governing Body in April 2013. The Business Committee has decided how to adopt the TAG recommendations and those decisions are detailed.

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 receive 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

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Adoption of Treatment Advisory Group Recommendations from April 2013

1. Background

1.1. The Business Committee has responded to the most recent recommendations from the Treatment Advisory Group (TAG).

1.2. 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.

1.3. The Treatment Advisory Group's Terms of Reference were circulated to Governing Body members in April 2013.

2. Recommendations

The Governing Body is asked to receive the decisions.

POLICY RECOMMENDATIONS FROM
TREATMENT ADVISORY GROUP meetings
8th April 2013

	Medicines & Technologies Board Recommendation	Vale of York CCG
1.	**Dapagliflozin for the management of type 2 diabetes mellitus to improve glycaemic control.** Recommendation: It is not recommended for the management of type 2 diabetes at this time. The decision was taken to wait for NICE guidance in June 2013 to identify its place in therapy. **Key points which were discussed include:** • Dapagliflozin is a first-in-class, orally-active, competitive, reversible inhibitor of the human sodium-glucose co-transporter 2 (SGLT2) to be licensed in the UK. • NICE are expected to publish the technical appraisal at the end of June 2013 • SMC have approved it but restricted to dual therapy in combination with metformin only when a sulphonureas is inappropriate. Did not support use in combination with insulin. • Monotherapy clinical trials showed dapagliflozin to be more effective than placebo but no head to head trials showed that it would be superior to metformin. • Combination of dapagliflozin with metformin was shown to be more effective compared to either as monotherpy. • It has the added benefit of causing weight loss so may be of benefit to obese patients. • It should be noted that there small numbers of elderly patients included in clinical trials. • Dapagliflozin increases diuresis and is not recommended in patients receiving loop diuretics. • Safety concerns relate to increase risk of UTIs and genital infections. FDA is also looking into a potential increase risk of breast and bladder cancer. • SPC states the following warnings: ➢ not recommended with CrCl<60ml/min. ➢ Not recommended in over 75s. ➢ Monitoring of renal function – baseline	**Not commissioned, await NICE guidance**

	then yearly and if approaching moderate/ severe renal impairment then consider every 2-4 times a day. ➢ Not recommended with loop diuretics ➢ Risk of falls in combination with ant-hypertensives or elderly with history of hypotension. ➢ Not recommended with pioglitazone. ➢ Not studied in combination with DPP-4 inhibitors and GLP analogues • Views from local consultants were not very supportive of this treatment and recommended to await NICE guidance so identify clear place in treatment pathway.	
2.	**Tadalafil for the treatment of the signs and symptoms of benign prostatic hyperplasia in adult males** Recommendation; Tadalafil is not recommended for the treatment of benign prostatic hyperplasia in adult males. There is no evidence to show it to be more effective than standard treatment for this condition. **Key points which were discussed include:** • Evidence shows that tadalafil may improve lower urinary tract symptoms associated with benign prostatic hyperplasia but is no more effective than the standard treatments recommended by NICE for this indication. • It is unlikely that this treatment would be shown to be cost effective compared to standard treatment such as alpha blockers and 5-alpha reductase inhibitors. • Both NICE and SMC were unable to provide a recommendation because of no evidence submission by the manufacturer. • Tadalafil may be beneficial in patients who suffer from both benign prostatic hypertrophy and erectile dysfunction. • Drug treatments for the management of erectile dysfunction can be provided on the NHS for the following conditions: diabetes, multiple sclerosis, Parkinson's disease, poliomyelitis, prostate cancer, prostatectomy, radical pelvic surgery, renal failure treated by dialysis or transplant, severe pelvic injury, single gene neurological disease, spinal cord injury, spina bifida (Ref HSC 1999/148.	**Not commissioned for treatment of benign prostatic hyperplasia**

3.	**Aflibercept for the treatment of wet age-related macular degeneration** Recommendation: It was not possible to provide a single recommendation that covers all CCGs. This was due to the following: • It will be required to determine how local ophthalmologists will treat patients with aflibercept in clinical practice (ie number of injections, monitoring visits. • It is not known whether the confidential discounted price for aflibercept is the same for all acute hospital trusts. • Locally agreed costs of current activity which includes monitoring visits and intravitreal administration will differ across all CCGs. • Therefore to calculate the cost impact of aflibercept compared to ranibizumab will need to be done on an individual CCG basis. **Key points which were discussed include:** • Aflibercept is a humanised VEGF receptor fusion protein which binds to all forms of VEGF-A and placenta growth factor. It is an alternative treatment to ranibizumab for the management of Wet age related macular degeneration. • Evidence from the VIEW studies, shows Aflibercept 2mg administered monthly for 3 months, followed by 2mg every two months up to one year, followed by PRN dosing between 1-3 monthly is as effective as ranibizumab. • At present the predicted number of injections over the first two years is likely to be similar in clinical practice but there is scope with aflibercept to extend the period between injections which may result in some patients needing fewer injections. This in turn could result in a reduction in administration associated adverse events. • Overall patients will need less monitoring appointments with aflibercept compared to ranibizumab, this will have a positive impact on clinical capacity and may prove more preferable to patients. • NICE are due to publish guidance at the end of August 2013. Since the TAG meeting, SMC have published their guidance which accepted alfibercept as a treatment option in Wet AMD in	**Commissioned. Implementation to be discussed with providers.**

	patients not previously treated with anti-VEGF therapy. • It was highlighted that was a regional procurement process been carried out at the moment which may result in a further reduction in price in ranibizumab. • Ophthalmologists may also wish to consider using aflibercept in the following group of patients: ➢ Patients requiring frequent retreatment with ranibizumab. Aflibercept may well reduce the frequency of treatments/ monitoring visits. ➢ Patients who have lost response to ranibizumab (ie second line treatment). ➢ Patients who are resistant or refractory to treatment with ranibizumab. It should be noted that the main clinical trials (VIEW 1 and 2) excluded patients who had previously been treated with anti-VEGF treatment so the evidence to support the use of aflibercept in these patient groups is very limited.	
4.	**NICE TA 276: Colistimethiate sodium and tobramycin dry powders for inhalation for treating pseudomonas lung infection in cystic fibrosis** NICE recommend both tobramycin DPI and colistimethate sodium DPI for treatment of chronic pulmonary infection caused by Pseudomonas aeruginosa in people with cystic fibrosis within criteria set out within the appraisal and the manufacturer provides it at the discount agreed as part of the patient access scheme. It should be noted that cystic fibrosis services are commissioned and funded by NHS England. The present national policy for cystic fibrosis inhaled treatments states that the discount rate on the dry powder inhalers is only available if supplied via hospital or home delivery services. Therefore GP shared care prescribing is not supported for the inhalers.	**Commissioning decision responsibility of Area Team, not CCGs**