NHS
City and Hackney
Clinical Commissioning Group

May 2013

PHOSPHODIESTERASE TYPE – 5 INHIBITORS (PD5-I) FOR THE TREATMENT OF ERECTILE DYSFUNCTION

A recent EPACT search highlighted the prescribing of a large volume of sildenafil tablets 50mg (112 tablets). When this was brought to the attention of the practice, further investigation identified the prescribing to be for the indication Raynauds Syndrome, advised by the rheumatology consultant at Homerton.

This incident flagged up two important issues regarding the prescribing of sildenafil and all other oral PD5-I:

- Prescribing within the licensed indication
- Quantities prescribed

Primary Care Prescribing within the Licensed Indication

Currently the only licensed indication of oral PD5-I prescribing which is approved for use in primary care is for the treatment of erectile dysfunction. This is the only indication for oral PD5-I which has been agreed locally by the Joint Prescribing Group which considers and decides on formulary issues.
Any requests for the prescribing of oral PD5-I, by secondary/ tertiary care, outside of the treatment of erectile dysfunction should be referred back to the initiating physician on the grounds that it is not formulary approved and often the indications are unlicensed.

Licensed Indication Other than for the Treatment of Erectile Dysfunction

Pulmonary Arterial Hypertension (PAH) is the only other licensed indication for sildenafil (*Revatio® brand of sildenafil*) and tadalafil (*Adcirca®brand of tadalafil*). Prescribing is restricted to specialist PAH centres and should remain the responsibility of the acute trusts which receive ongoing funding for supplying patients with ongoing prescriptions for this use. There should be no subsequent charges of drug costs to the PCT for PAH prescribing of sildenafil or tadalafil.

Tadalafil 5mg (Cialis®) has recently been granted a licence for the treatment of the signs and symptoms of Benign Prostatic Hyperplasia (BPH). This indication has not been presented to the Joint Prescribing Group.

Quantities Prescribed

Limitations to the quantities of oral PD5-I that should be prescribed were introduced by the DoH. These medicines have the potential for abuse and diversion and have been found to have a "street value" for men who consider, rightly or wrongly, that these treatments will enhance their sexual performance and that excessive prescribing could therefore lead to unlicensed, unauthorised and possibly dangerous use of these treatments.

The DoH has advised that oral PD5-I prescribing should be restricted to one treatment per week for erectile dysfunction. This recommendation was based on research showing that the average frequency of sexual intercourse in the age range of 40-60years was once per week.

If a GP in exercising his/her clinical judgement considers that more than one treatment a week is appropriate, s/he should prescribe that amount on the NHS.

If a clinician has decided that a patient requires treatment for an indication outside of the DoH guidance or local Joint Prescribing Group formulary decisions then, prescribing will remain the responsibility of the acute trust with no subsequent charges of drug costs or activity to the PCT. GPs should not be asked to prescribe for patients in these circumstances, as patients not meeting the NHS criteria will not be entitled to an NHS prescription.

Prescribing on the NHS

PD5-I drugs used for ED are not available on the NHS unless the patients meets the criteria laid down by the Department of Health (DoH) as described in the Health Service Circular

- have diabetes, multiple sclerosis, Parkinson's disease, poliomyelitis, prostate cancer, severe pelvic injury, single gene neurological disease, spina bifida, or spinal cord injury;
- are receiving dialysis for renal failure;
- have had radical pelvic surgery, prostatectomy (including transurethral resection of the prostate), or kidney transplant;
- were receiving *Caverject*®, *Erecnos*®, *MUSE*®, *Viagra*®, or *Viridal*® for erectile dysfunction, at the expense of the NHS, on 14 September 1998;
- are suffering severe distress as a result of impotence (prescribed in specialist centres only, see below)

Specialist centres can prescribe PD5-I if the man is 'suffering severe distress as a result of impotence' that causes:

- Significant disruption to normal social and occupational activities.
- A marked effect on mood, behaviour, social, and environmental awareness.
- A marked effect on interpersonal relationships

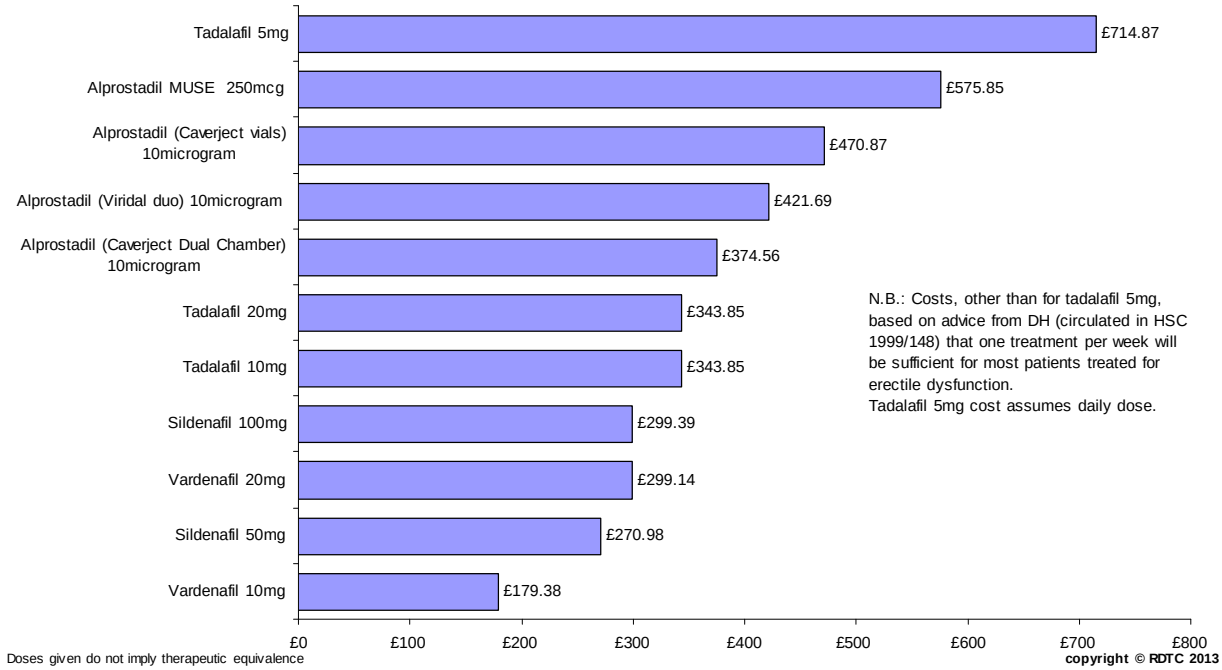
Any prescribing initiated by specialist services must remain with the specialist centre. GPs can continue prescribing for this indication if the patient subsequently meets any of the other criteria stipulated by the DoH List e.g. a diagnosis of diabetes is made.

Prescriptions for patients that meet the DoH criteria (*Prescribing on the NHS List*) for NHS provision must be endorsed 'SLS'. Prescribers must not endorse an NHS Prescription with 'SLS' if a patient does not meet any of the NHS criteria. Pharmacy contractors' terms of service will not allow them to dispense a prescription for any of the drugs in question under NHS pharmaceutical services arrangements, unless the prescriber has endorsed the prescription with 'SLS'.

Formulary

- Sildenafil is the formulary choice PD5-I (The patent for Viagra® is due to expire in June 2013) for the treatment of erectile dysfunction. Current evidence does not favour any specific PD5-I over another for PRN intermittent use.
- Tadalafil (Cialis®) 10mg and 20mg preparations are non-formulary and should not be routinely prescribed.
- Daily tadalafil (2.5mg and 5mg) is approved only for penile rehabilitation following radical prostatectomy.

January 2013: Drugs for erectile dysfunction - cost of 1 year's treatment (Regional Drug and Therapeutics Centre Cost Comaprison Chart January 2013)



Non-responders

- Approximately 25% of patients do not respond to PD5-I.
- Patients should be given a trial of at least 4 doses (preferably 8 doses) prescribed once weekly, of the highest tolerated dose with adequate sexual stimulation before being declared non-responsive
- A trial of an alternative PD5-I is suggested before considering other options. Possible reasons for failure should be explored which may be non-drug related.
- In patients who do not have an adequate response, the following should also be considered:
  - Re-counselling on proper use of the medication
  - Optimal treatment of concurrent diseases and frequent re-evaluation for new risk factors
  - Treatment of concurrent hypogonadism if applicable

TREATMENT PATHWAY FOR ERECTILE DYSFUNCTION

1st line: Oral Phosphodiesterae Type 5 Inhibitors (if comorbidities present, refer to dosage in BNF)

- Generic Sildenafil 100mg tablet once weekly PRN is considered 1st choice oral PDI-5. Titrate dose down to 25mg – 50mg once weekly prn according to patients' response and side effects.

- If non-responsive following adequate trial and advice, consider alternative PDI-5 Vardenafil 20mg tablet once weekly prn (titrate dose to 5mg-10mg once weekly prn according to patients response and side-effects)

Consider daily tadalafil (2.5mg-5mg) only:

- If patient experiences severe headaches, muscle cramps, myalgia with any PDI-5 weekly dosing
- If patient anticipates more than twice weekly sexual activity **and** has been successful in response to on demand prn weekly dosing

2nd line: Refer
Where patient has failed to respond to the maximum dose of two PDI-5, refer to specialist.

Treatments suitable for prescribing by general practitioner, following initiation by specialist include:

- Vacuum device therapy (may be used in combination with PDI-5) – patient will be provided training on how to use at HUHT. GPs will be requested to prescribe on FP10 by secondary care.
- Intracavernous alprostadil (*Caverject® or Viridal Duo®*)
- Intraurethral alprostadil (MUSE®)

Erectile Dysfunction Following Radical Prostatectomy (RP)

- For patients who were able to have an erection pre RP;

6 weeks treatment of tadalafil 5mg daily post RP (Full treatment course will be provided by secondary care)

Sildenafil 100mg PRN TWICE WEEKLY +/- Vacuum Pump Device (on request from secondary care) to be prescribed by GP. Titrate according to response and side effects.

- Patients being treated for ED pre RP will resume with their normal treatment after the 6 week tadalafil course.

References

1. NHS Herefordshire, Prescribing Newsletter Oct 2012 No. 49
2. NHS Camden, erectile Dysfunction Prescribing Advice 22nd November 2007
3. BNF No 65 March 2013
4. Regional Drug and Therapeutics Centre Cost Comparison Charts 2013 http://www.nyrdtc.nhs.uk/docs/cost_comparison_charts.pdf

APPROVAL PROCESS

Written By	Shaista Hussain, Prescribing Advisor
Version:	1.0
Consultation Process	Ms J Pati (Consultant Urologist), Medicines Management Team City & Hackney
Ratified By	Joint Prescribing and Medicines Management Group (May 2013)
Review Date:	May 2015