Surrey Heartlands Integrated Care System
Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North West Surrey, and East Surrey Places & associated partner organisations.

Application for medicines described in CKS, NICE guidance and/or other national guidance

Name of guidance[1]	**Erectile dysfunction - Prescribing Information**
Available at	• For treatment pathway, and all treatments unless indicated below: https://cks.nice.org.uk/topics/erectile-dysfunction/ • For aviptadil/ phentolamine (Invicorp) , Scottish Medicines Consortium: https://www.scottishmedicines.org.uk/medicines-advice/aviptadilphentolamine-mesilate-invicorp-fullsubmission-128417/ • For daily tadalafil, removed from NHSE ;Items which should not routinely be prescribed in primary care (FAQ)

The APC will have 4 options when asked to consider the application/s:

1. To accept
2. To reject
3. To allocate alternative traffic light classification
4. To request a full evidence review.

The traffic light status for the Surrey PAD is available at: Traffic Light Status (res-systems.net)

Background:

The erectile dysfunction treatment pathway was last revised by the Area Prescribing Committee in September 2018

A review is required for the following reasons:

1. CKS was updated in January 2024, changes can be seen on the CKS website (Link) Changes have been minor, but reflect a literature search conducted in November 2022 to identify evidence-based guidelines, UK policy, systematic reviews, and key randomized controlled trials (RCTs) published since the last revision of this topic. The topic has undergone minor restructuring to improve clarity and navigation. No major changes to clinical recommendations have been made. Detail about phosphodiesterase-5 (PDE-5) inhibitor dose escalation if initial treatment is ineffective or unsatisfactory has been added in the section on Follow-up.
2. A request was made by specialists to add aviptadil/phentolamine (Invicorp®) as a treatment option, as this injectable preparation appears to be less painful than the other injectable options currently approved at the Area Prescribing Committee
3. Daily tadalafil is no longer listed in the NHSE 'Items which should not routinely be prescribed in primary care: policy guidance'. Local guidance should reflect this change
4. Currently, only sildenafil is approved for penile rehabilitation. This restriction was based on cost when compared to tadalafil. With the price drop of tadalafil, it is proposed that, for the purpose of penile rehabilitation, sildenafil and tadalafil have equal first place in therapy.
5. Due to the low cost of sildenafil and tadalafil, is it reasonable to allow more than 1 dose per week? May reduce need for daily 2.5mg tadalafil.

Initial proposal was to remove the ED pathway in Primary Care, September 2018, from the PAD (Link), however in pre-consultation there were several comments supporting the pathway – APC to consider whether to update with current decisions or whether to remove.

This paper will:

1. Propose a new approval for aviptadil/phentolamine (Invicorp®)
2. Propose an updated statement on daily tadalafil* (may require different decisions for the 5mg and 2.5mg doses)
3. Add tadalafil as a treatment option for penile rehabilitation
4. Summarise the currently approved Formulary section for erectile dysfunction,confirming current traffic light classification
5. Update old traffic light classification from amber to **BLUE,** and from BLACK to non-Formulary and Do not prescribe
6. Change traffic light classification for alprostadil urethral sticks from **BLUE** for initiation by specialists to either **BLUE** on advice by specialists or **GREEN**

Medicine name (generic and brand)	State licensed indication and if use in this application is licensed?	Place in therapy	Does it require dose titration?	Does it require monitoring? (SPC and SBS monitoring)	Recommended traffic light	Comments Must include information about: • whether a cost impact is expected and by how much. • impact on workload, e.g. monitoring.
Aviptadil 25microgram/ Phentolamine 2mg (Invicorp®) solution for injection	For the symptomatic treatment of erectile dysfunction in adult males due to neurogenic, vasculogenic, psychogenic, or mixed aetiology.	For use in those who have failed on oral therapies (oral phosphodiesterase type-5 inhibitors) and other non-injectable formulations of erectile dysfunction medications	No	No SLS only	**NEW:** **BLUE**	Evidence as approved by SMC (Link) Cost similar to other injectable treatments so do not expect cost increase. Currently approx. 800 prescrptions in SH per year at a cost of £50K Note that Invocorp® comes in packs of 5 and not 1's and 2's as other injectables
Alprostadil (Caverject® Viridal Duo®, Caverject Dual Chamber®)	Treatment of erectile dysfunction in adult males due to neurogenic, vasculogenic, psychogenic or mixed aetiology.	For use in those who have failed on oral therapies (oral phosphodiesterase type-5 inhibitors) and other non-injectable formulations of erectile dysfunction medications	No, but dose increases may be required	No SLS only	**No Change:** **BLUE**	
Alprostadil Stick MUSE®	Treatment of erectile dysfunction in adult males due to neurogenic, vasculogenic, psychogenic or mixed aetiology.	For use in those who have failed on oral therapies (oral phosphodiesterase type-5 inhibitors)	No, but dose increases may be required	No SLS only	Change from **BLUE** for initiation by specialists to either **BLUE** on advice by specialists or **GREEN** After alprostadil cream	I would support MUSE as Blue- on advice as the vast majority of patients trying the intraurethral MUSE pellet have already tried intraurethral Vitaros & so are adept at intraurethral insertion & so do not need a demonstration on how to insert MUSE.

Alprostadil cream (Vitaros®)	Treatment of men ≥ 18 years of age with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.	For patients who do not respond to PDE-5 inhibitors.	No	No SLS only	**No Change:** **GREEN**	
Sildenafil	Indicated in adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance	=1st line	No, but dose increases may be required	No	**No Change:** **GREEN**	For patients who do not meet SLS criteria, only sildenafil is currently approved for prescribing for those patients
Tadalafil for 'as required' use	Treatment of erectile dysfunction in adult males.	Change to = 1st line from 2nd line	No, but dose increases may be required	No SLS only	**New Place in therapy** **GREEN**	
Tadalafil for 'daily' use	Treatment of erectile dysfunction in adult males.	NHSE restriction removed on the basis that costs are comparable to 'as required medication' but notes that there may be considerable cost differences . 5mg cost is comparable to other treatments, 2.5mg still much more expensive.	No, but dose reduction may be required from 5mg initial dose	No SLS only	5mg daily tadalafil **New Place in therapy** **GREEN** 2.5mg daily tadalafil **No Change:** Non-Formulary: use 'as required doses	

Vacuum pump	Treatment of erectile dysfunction in adult men	Most useful in patients with nerve damage, whether by surgery or for medical reasons.	No	No SLS only	**GREEN**	
Vardenafil	Treatment of erectile dysfunction in adult men. Erectile dysfunction is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.	More expensive than sildenafil and tadalafil, long acting like tadalafil, but interacts with food so no advantage	No, but dose increases may be required	No SLS only	**No Change:** Non- Formulary	Now available as a generic. For patients unwilling to change to tadalafil, ensure generic prescribing
Avanafil	Treatment of erectile dysfunction in adult men.	More expensive than sildenafil and tadalafil, no place in Therapy identified	No, but dose increases may be required	No SLS only	**No Change:** Non- Formulary	Branded only in drug tariff
Sildenafil	Penile rehabilitation		Dose to be recommended by specialists	No	**Change of traffic light classification from Amber* to BLUE**	
Tadalafil	Penile rehabilitation	As price is now similar to sildenafil, allow use for penile rehabilitation	Dose to be recommended by specialists (not daily 2.5mg)	No SLS only	**New:** **BLUE**	

References:

1. Aviptadil with phentolamine mesilate | Drugs | BNF | NICE
2. Prescribing information | Erectile dysfunction | CKS | NICE
3. Surrey PAD Guidelines : Erectile dysfunction (res-systems.net)
4. Bulletin 322: Tadalafil once daily | PrescQIPP C.I.C
5. Aviptadil/phentolamine mesilate (Invicorp) (scottishmedicines.org.uk)
6. Dr N Valentine, Psychosexual Medicine, Urology Department, RSCH (verbal communication and written statement re: Muse)*
7 . Mr. Dimitrios Moschonas, Consultant Urologist, Clinical Lead, RSFT (verbal communication)*

*Further discussion regarding penile rehabilitation to be presented at future APC.

Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by	KM	MRU UNIT Ph tech	April 2024	None
Reviewed by	CJ	MRU UNIT Lead Pharmacist	April 2024	None

Explanation of declaration of interest:
None.

Appendix 1 Cost comparison: *Cost per month is for 4 doses per month, unless endorsed with (Daily) in which case the cost is for 28 doses*