

<b>GENERAL POLICY</b>	<b>Policy Ref: 25/10</b>
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<b>Treatment (brand name, manufacturer):</b>	Penile prostheses
<b>For the treatment of:</b>	Erectile Dysfunction
<b>Background:</b>	Penile prostheses are occasionally requested by specialists for the treatment of erectile dysfunction but the PCT currently has no policy for their funding.
<b>Commissioning position:</b>	<p>Penile implants are routinely funded for the treatment of severe organic erectile dysfunction (ED) with the following restrictions:</p> <ul style="list-style-type: none"> <li>▪ as third line treatment ONLY following adequate trials of standard therapies (including oral PDE-5 inhibitors, testosterone replacement), vacuum constriction device, and intracavernous injection therapy and intraurethral alprostadil.</li> <li>▪ ED is associated with one of the following medical conditions: Diabetes; Multiple Sclerosis ; Parkinson's Disease ; Poliomyelitis ; Prostate Cancer ; Prostatectomy ; Radical Pelvic Surgery ; Severe Pelvic Injury ; Renal Failure treated by dialysis or transplant ; Single Gene Neurological Disease ; Spinal Cord Injury ; Spina Bifida OR</li> <li>▪ there is documented evidence the patient is suffering severe distress on account of their ED</li> <li>▪ Appropriate risk factor modification and lifestyle changes such as losing weight, stopping smoking, reducing alcohol consumption, and increasing exercise should have been tried</li> <li>▪ Psychological assessment has been done and has excluded a treatable underlying psychogenic cause.</li> <li>▪ Urological assessment has been done and has excluded</li> </ul>

	<p>a treatable underlying physical abnormality.</p> <ul style="list-style-type: none"> <li>▪ Endocrine assessment has been done and has excluded a treatable underlying hormonal cause.</li> </ul>																																				
<b>Effective from:</b>	24 <sup>th</sup> September 2010																																				
<b>Summary of evidence:</b>	<p>Erectile dysfunction is defined as the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance. It is more common in older men, affecting about half the male population of 40–70 years of age.</p> <p>(PDE-5) inhibitors are effective in approximately 75% of patients, and for non-responders second and third line therapies can be offered.</p> <p>There is considerable evidence that adequate levels of testosterone are required for ED therapies, especially PDE5 inhibitors, to achieve maximal response and in many cases normalisation of testosterone levels can restore erectile function.</p> <table border="1"> <thead> <tr> <th>Recommendation</th> <th>LE</th> <th>GR</th> </tr> </thead> <tbody> <tr> <td>Lifestyle changes and risk factor modification must precede or accompany ED treatment</td> <td>1b</td> <td>A</td> </tr> <tr> <td>Pro-erectile treatments have to be given at the earliest opportunity after radical prostatectomy</td> <td>1b</td> <td>A</td> </tr> <tr> <td>When a curable cause of ED is found, the cause must be treated first</td> <td>1b</td> <td>B</td> </tr> <tr> <td>PDE5 inhibitors are first-line therapy</td> <td>1a</td> <td>A</td> </tr> <tr> <td>Daily administration of PDE5 inhibitors may improve results and restore erectile function</td> <td>1b</td> <td>A</td> </tr> <tr> <td>Inadequate/incorrect prescription and poor patient education are the main causes of a lack of response to PDE5 inhibitors</td> <td>3</td> <td>B</td> </tr> <tr> <td>Testosterone replacement restores efficacy in hypogonadic non-responders to PDE5 inhibitors</td> <td>1b</td> <td>B</td> </tr> <tr> <td>Apomorphine can be used in mild-to-moderate ED or psychogenic causes or in patients with contraindications for the use of PDE5 inhibitors</td> <td>1b</td> <td>B</td> </tr> <tr> <td>A vacuum constriction device can be used in patients with stable relationship</td> <td>4</td> <td>C</td> </tr> <tr> <td>Intracavernous injection is second-line therapy</td> <td>1b</td> <td>B</td> </tr> <tr> <td>Penile implant is third-line therapy</td> <td>4</td> <td>C</td> </tr> </tbody> </table> <p>LE = level of evidence GR = grade of recommendation (Ref 3)</p> <p>NHS Evidence - Clinical Knowledge Summaries ; Erectile</p>	Recommendation	LE	GR	Lifestyle changes and risk factor modification must precede or accompany ED treatment	1b	A	Pro-erectile treatments have to be given at the earliest opportunity after radical prostatectomy	1b	A	When a curable cause of ED is found, the cause must be treated first	1b	B	PDE5 inhibitors are first-line therapy	1a	A	Daily administration of PDE5 inhibitors may improve results and restore erectile function	1b	A	Inadequate/incorrect prescription and poor patient education are the main causes of a lack of response to PDE5 inhibitors	3	B	Testosterone replacement restores efficacy in hypogonadic non-responders to PDE5 inhibitors	1b	B	Apomorphine can be used in mild-to-moderate ED or psychogenic causes or in patients with contraindications for the use of PDE5 inhibitors	1b	B	A vacuum constriction device can be used in patients with stable relationship	4	C	Intracavernous injection is second-line therapy	1b	B	Penile implant is third-line therapy	4	C
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	<p>Dysfunction <a href="http://www.cks.nhs.uk/erectile_dysfunction">http://www.cks.nhs.uk/erectile_dysfunction</a></p> <p>Guidelines on the management of erectile dysfunction, British Society for Sexual Medicine (BSSM) Hackett et al, 2008. <a href="http://www.bssm.org.uk/downloads/BSSM_ED_Management_guidelines_2007.pdf">http://www.bssm.org.uk/downloads/BSSM_ED_Management_guidelines_2007.pdf</a></p> <p>European Association of Urology 2009. Male Sexual Dysfunction: Erectile dysfunction and premature ejaculation. Wespes, E et al. <a href="http://www.uroweb.org/fileadmin/tx_eauguidelines/2009/Full/Male_Sexual_Dysf.pdf">http://www.uroweb.org/fileadmin/tx_eauguidelines/2009/Full/Male_Sexual_Dysf.pdf</a></p> <p>NICE CG 66 Type 2 Diabetes <a href="http://www.nice.org.uk/nicemedia/pdf/CG66FullGuideline0509.pdf">http://www.nice.org.uk/nicemedia/pdf/CG66FullGuideline0509.pdf</a></p>
<b>Equality Impact:</b>	No formal EIA required.
<b>Date approved by SCG Board:</b>	24 <sup>th</sup> September 2010
<b>Policy to be reviewed by:</b>	24 <sup>th</sup> September 2012
<b>Version:</b>	1
<b>Supersedes:</b>	N/A
<b>Date approved by CSSG/RPSG:</b>	CSSG: 9 <sup>th</sup> September 2010
<b>Responsible Officer /Contact:</b>	NHS Hull
<b>Distribution /Target Audience:</b>	<p>IFR Managers  Directors of Commissioning  Directors of Public Health  Contracting Leads  PCT Nominated Officers  SHA – (Chris Welsh, Michelle Cossey)</p> <p>cc: Cancer Networks</p>