

# Please answer the following questions or explore questions as part of your patient discussion.

#### **Patient Goals**

- What decision is the patient facing with their sexual health?
- What is the patient's personal goal related to their sexual health?
- Is the patient alone making this decision or are they making the decision with a partner?

an erection.

- What are the patient's reasons for making this decision?
- How far along is the patient in making this decision?

#### **Treatment Options**

Patient treatment option discussions should include patient satisfaction and outcomes, possible side effects, product characteristics and typical duration of use. You can then discuss each option as to which treatment best meets the patient's needs and the needs of their partner.

- Does the patient understand the product options and characteristics for each treatment pathway?
- Does the patient understand the patient satisfaction rates and outcomes and any possible side effects of each treatment pathway?

### Support

- Who else is involved in this treatment decision?
- Does the patient have good support at home?
- Is he or she willing to assist the patient in the decision making?
- Are there any other concerns or questions the patient may have with their decision?
- Does the patient need any further discussion or education on the treatment pathways?

#### **Next Steps**

 Food Interaction: should refer to each PDE5-Inhibator prescribing informative for interactions with food

- Review ED treatment options to make sure the patient has a good understanding of each.
- Educate on additional resources, such as websites (EDCure.org), books and videos.
- Provide necessary educational materials.
- Visit EDCure.org to find and refer to a local ED specialist in their area.

EDCure.org is a website sponsored by Boston Scientific.

| and any possible side effects of each treatment pathway?   |   |   |  |  |
|--|---|---|--|--|
|  | Patient satisfaction and outcomes   | Possible side effects   | Product characteristics  | Typical duration of use  |
| Penile implants  In use since the 1970s, penile implants have helped hundreds of thousands of men return to an active sex life.¹ A penile implant is a medical implant that is implanted into the penis during an outpatient procedure. The implant is entirely concealed within the body. To operate, one squeezes and releases the pump, located in the scrotum, to achieve an erection. To return the penis to a natural flaccid state, the deflate button located on the pump bulb is depressed. | <ul> <li>184 of 200 men (92%) said sexual activity with the implant was "excellent" or "satisfactory"<sup>2</sup></li> <li>115 of 120 partners (96%) said sexual activity with the implant was "excellent" or "satisfactory"<sup>2</sup></li> <li>196 of 200 patients (98%) reported erections to be "excellent" or "satisfactory"<sup>2</sup></li> <li>97% of patients would recommend a penile implant to a friend<sup>3</sup></li> </ul> | <ul> <li>Latent, natural erections no longer possible</li> <li>Infection (&lt;1% risk) requires removal of device</li> <li>Mechanical failure</li> <li>Pain (typical with healing process)</li> </ul> | <ul> <li>Permanent ED treatment</li> <li>Concealed within the body</li> <li>Maintain erection as long as desired</li> <li>Spontaneous sex when the mood strikes</li> <li>Doesn't interfere with orgasm or ejaculation</li> </ul> | <ul> <li>98% of penile implants are in use after 1.5 to 5 years<sup>2,5</sup></li> <li>At 7 years, 94% are still in use and free from revision<sup>6</sup></li> </ul>  |
| Vacuum erection DEVICES (VEDs)  In use since the 1980s, a vacuum erection device consists of a hollow plastic tube, a vacuum pump and a tension ring. With the tube placed over the penis, the pump creates a vacuum that pulls blood into the penis. Once an erection is achieved, an elastic tension ring is placed at the base of the penis to help maintain the erection.  | <ul> <li>VED patient satisfaction rates range from 68-80%<sup>7</sup></li> <li>VED success rates range from 80-92% after radical prostatectomy<sup>8</sup></li> </ul>   | Penile bruising/burst blood vessels Penile pain/discomfort Penile numbness Delayed ejaculation or failure to ejaculate Cool or different colored erection   | <ul> <li>Non-invasive</li> <li>Drug free</li> <li>Cost effective</li> </ul>  | Despite initial high success rates, in a study<br>of 85 patients, 73 of 85 (86%) decided<br>to move onto other sexual aids <sup>8</sup>  |
| Self-injections In use since the 1980s, injection therapy uses a needle to inject medication directly into the base or side of the penis. These medications improve blood flow into the penis to cause an erection.  | <ul> <li>~60% of patients were satisfied and continued use<sup>13</sup></li> <li>Satisfaction for men and partners at 4 years was 91.4%<sup>14</sup></li> <li>Clinical studies report ~60-86% success rates<sup>14,15</sup></li> </ul>  | Penile pain Prolonged erection Penile fibrosis Injection site hematoma Penile curvature Palpable plaque   | • Injected with a needle into the corpus cavernosum • Onset of erection: 5-20 mins • Refrigeration required  | <ul> <li>Despite success rates, in a study of 294 men, only 59 (20%) continued the therapy<sup>14</sup></li> <li>107 (45.5%) men discontinued at 6 months, and 151 (64.2%) men discontinued at 12 months<sup>14</sup></li> <li>Another study found 40% drop out rate at 12 months, and 70% at 43 months for post prostatectomy patients<sup>8</sup></li> </ul> |
| Intraurethral suppositories In use since the 1990s, intraurethral suppository treatment for ED uses an applicator containing a small pellet that is inserted into the urethra. Once the pellet is released, it dissolves to increase blood flow to the penis to form an erection.  | <ul> <li>Clinical study satisfaction rates are limited, but one study found 64 of 192 men (33%) were satisfied<sup>17</sup></li> <li>In clinical literature, success rates are reported at 40-65%<sup>18,19</sup></li> </ul>  | Penile pain Urethral pain or burning Urethral bleeding/spotting Dizziness Hypotension   | No needles     Onset of erection: 5-10 minutes     Refrigeration required  | <ul> <li>In one study of 54 patients, over half discontinued use after 8 months<sup>21</sup></li> <li>Another clinical study reported 40-50% of men don't continue using this therapy after 6-8 months<sup>8</sup></li> </ul>  |
| Oral Medications  Most men with ED start with pills, such as Viagra™, Levitra™, Cialis™ and Stendra™. These may improve blood flow to the penis, and with sexual stimulation, can help you achieve an erection   | • Effective in ~70% of cases but less effective in patients with diabetes or damage to the nerves or endothelium. 8,25  | <ul> <li>Dyspepsia</li> <li>Back pain</li> <li>Myalgia</li> <li>Nasal congestion</li> <li>Flushing</li> <li>Pain in limb</li> </ul>   | Non-invasive     Available in different dosages and strengths     Onset of erection: 30 minutes to 1 hour  Food lateractions should refer to each PDES labilitates.  | • Some men cannot achieve a satisfactory erection with pills and other men will switch the type of pills to achieve a satisfactory outcome. <sup>8,25</sup>  |

Administration of PDE5-inhibators to patients using any form of organic nitrate

is contraindicated

The American Urological Association (AUA) released a new clinical guideline and algorithm on the diagnosis, treatment and management of erectile dysfunction (ED), strongly suggesting the physician, patient and partner engage in a shared decision-making process to select the best care option for each individual patient and their partner. Available online at www.auanet.org/guidelines/male-sexual-dysfunction-erectile-dysfunction-(2018).

This new methodology outlines the process to identify and treat ED, with an emphasis on the importance of fully understanding the benefits and risks of all treatment options, and the consideration of all treatment options as a valid first-line therapy.

- · Advise and counsel the man and partner on treatment benefits and risks, and lifestyle choices that could impact sexual and overall health
- Actively engage in a shared decision-making process to select the best treatment option for each individual man and partner
- Assess the outcomes and efficacy of treatment
- Address adjustments to treatment or consider alternate treatment

## Tier 1 treatment options for men with erectile dysfunction

Oral medications **Vacuum** erection devices

Muse urethral suppository

**Penile** injections

**Penile** prosthesis

# 15.3 million

According to the 2015 Census data. 15.3 million men in the US have diabetes<sup>26</sup>, and ED occurs 10–15 years earlier in men with diabetes<sup>27</sup> 46%

At one year following robotic assisted radical prostatectomy up to 46% of men have persistent ED<sup>28</sup>

Over a 2-year observation period. men with ED and diabetes were 50% more likely to require secondary ED treatments<sup>29</sup>

3-5 Years

cardiovascular event, such as a heart attack, may likely occur<sup>30,31</sup>

- $Penile prosthesis. \underline{www.essm.org/society/esha/malesd/oraltreatments/penileprosthesis.html.\ European\ Society\ for\ Sexual\ Medicine\ (ESSM).}$ Accessed January 1, 2013.
- Montoris F, Rigatti P, Carmignani G, et al. AMS three-piece inflatable implants for erectile dysfunction: a long-term multi-institutional study in 200 consecutive patients. Eur Urol. 2000 Jan;37(1):50-5.
- Bernal RM, Henry GD. Contemporary patient satisfaction rates for three-piece inflatable penile prostheses. Adv Urol. 2012;2012:707321.
- AMS 700" with MS Pump" Series Inflatable Penile Prostheses Patient Manual. Information and Instructions for Patients Considering an Inflatable Penile Prosthesis. American Medical Systems, Inc. 2016.
- AMS 700™ Penile Prosthesis Product Line Instructions for Use. American Medical Systems, Inc. 2016.
- 6. Enemchukwu EA, Kaufman MR, Whittam BM, et al. Comparative revision rates of inflatable penile prostheses using woven Dacron \* Fabric Cylinders. J Urol. 2013 Dec;190(6):2189-93.
- Defade BP, Carson CC 3rd, Kennelly MJ. Postprostatectomy erectile dysfunction: the role of penile rehabilitation. Rev Urol. 2011;13(1):6-13.
- 8. Matthew AG, Goldman A, Trachtenberg J, et al. Sexual dysfunction after radical prostatectomy: prevalence, treatments, restricted use of treatments and distress. J Urol. 2005 Dec;174(6):2105-10.
- The Process of Care Consensus Panel. The process of care model for evaluation and treatment of erectile dysfunction. Int J Impot Res. 1999 Apr;11(2):59-70. 10. Phé V, Rouprêt M. Erectile dysfunction and diabetes: A review of current evidence-based medicine and a synthesis of the main available therapies.
- Diabetes Metab. 2012 Feb;38(1):1-13. 11. Miner MM, Kuritzky L. Erectile dysfunction: a sentinel marker for cardiovascular disease in primary care. Cleve Clin J Med. 2007 May;74(Suppl 3):S30-7. Review.
- 12. Yuan J, Hoang AN, Romero CA, et al. Vacuum therapy in erectile dysfunction --science and clinical evidence. Int J Impot Res. 2010 Jul-Aug; 22(4):211-9. 13. Kerfoot WW, Carson CC. Pharmacologically induced erections among geriatric men. J Urol. 1991 Oct;146(4):1022-4.
- 14. Sung HH, Ahn JS, Kim JJ, et al. The role of intracavernosal injection therapy and the reasons of withdrawal from therapy in patients with erectile dysfunction in the era of PDE5 inhibitors. Andrology. 2014 Jan;2(1):45-50.
- 15. Ishii N, Watanabe H, Irisawa C, et al. Intracavernous injection of prostaglandin E1 for the treatment of erectile impotence. J Urol. 1989 Feb;141(2):323-5.
- 16. Caverject™ Prescribing Information. Pharmacia & Upjohn Company. Revised March 2014.
- 17. Mydlo JH, Volpe MA, MacChia RJ. Results from different patient populations using combined therapy with alprostadil and sildenafil: predictors of satisfaction. BJU Int. 2000 Sep;86(4):469-73
- 18. Padma-Nathan H, Hellstrom WJ, Kaiser FE, et al. Treatment of men with erectile dysfunction with transurethral alprostadil. Medicated Urethral System for Erection (MUSE) Study Group. N Engl J Med. 1997 Jan 2;336(1):1-7.
- 19. Costabile RA, Spevak M, Fishman IJ, et al. Efficacy and safety of transurethral alprostadil in patients with erectile dysfunction following radical prostatectomy.
- 20. MUSE™ Prescribing Information, Meda Pharmaceuticals, Inc. Revised March 2011,
- Nandipati KC, Raina R, Agarwal A, et al. Erectile dysfunction following radical retropubic prostatectomy: epidemiology, pathophysiology and pharmacological management. *Drugs Aging*. 2006;23(2):101-17.
   Viagra<sup>™</sup> Prescribing information. Pfizer, Inc. Revised January 2010.
- 23. Levitra™ Prescribing information. Bayer HealthCare Pharmaceuticals. Revised November 2011.
- 24. Cialis™ Prescribing information. Lily USA, LLC. Revised October 2011.
- 25. Stendra™ Prescribing Information. Vivus, Inc. 2014.
- $26.2011-2014\ National\ Health and\ Nutrition\ Examination\ Survey\ applied\ to\ 2015\ U.S.\ Census\ Bureau\ data.\ https://www.cdc.gov/diabetes/pdfs/data/statistics/data/s$ national-diabetes-statistics-report.pdf. Accessed July 27, 2018.
- 27. Malavige LS, Levy JC. Erectile dysfunction in diabetes mellitus. J Sex Med. 2009 May;6(5):1232-47.
- 28. Ficarra V, Novara G, Ahlering TE, et al. Systematic review and meta-analysis of studies reporting potency rates after robot-assisted radical prostatectomy. Eur Urol. 2012 Sep;62(3):418-30.
- 29. Walsh TJ, Hotaling JM, Smith A, et al. Men with diabetes may require more aggressive treatment for erectile dysfunction. Int J Impot Res. 2014 May-Jun;26(3):112-5.
- 30. Vlachopoulous C, Jackson G, Stefanadis C, et al. Erectile dysfunction in the cardiovascular patient. Eur Heart J. 2013 Jul;34(27):2034-46.
- 31. Jackson G, Boon N, Eardley I, et al. Erectile dysfunction and coronary artery disease prediction: evidence-based guidance and consensus. Int J Clin Pract.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

All images are the property of Boston Scientific. All trademarks are the property of their respective owners



**Boston Scientific Corporation** 300 Boston Scientific Way Marlborough, MA 01752 www.bostonscientific.com

© 2018 by Boston Scientific Corporation or its affiliates. All rights reserved.

MH-560610-AB OCT 2018