Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Subcutaneous Hormonal Implants [Testopel (testosterone pellets)]

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Testopel (testosterone pellets) for subcutaneous implantation Estrogen and estrogen containing combination subcutaneous implanted agents*

APPROVAL CRITERIA

Requests for Testopel (subcutaneous testosterone implants) **for hormone replacement therapy** may be approved if the following criteria are met:

I. Individual is male; **AND**
II. Individual is 18 years of age or older; **AND**
III. Prior to starting testosterone therapy, an initial and a repeat (at least 24 hours apart) morning total testosterone level confirms a low testosterone serum level indicating one of the following:
    A. Individual is 70 years of age or younger with a serum testosterone level of less than 300 ng/dL; **OR**
    B. Individual is over 70 years of age with a serum testosterone level of less than 200 ng/dL;

AND

IV. Individual has a diagnosis of one of the following conditions:
    A. Primary hypogonadism (congenital or acquired) (for example, bilateral torsion, cryptorchidism, chemotherapy, Klinefelter Syndrome, orchitis, orchiectomy, toxic damage from alcohol or heavy metals, vanishing testis syndrome, idiopathic primary hypogonadism, age-related hypogonadism [also referred to as late-onset hypogonadism]); **OR**
    B. Hypogonadotropic hypogonadism (also called secondary hypogonadism) (congenital or acquired), (for example, idiopathic gonadotropic or luteinizing hormone-releasing hormone [LMRH] deficiency, pituitary-hypothalamic injury);

AND

V. Individual presents with symptoms associated with hypogonadism, such as, but not limited to at least one of the following:
    A. Reduced sexual desire (libido) and activity; **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

B. Decreased spontaneous erections; **OR**
C. Breast discomfort/gynecomastia; **OR**
D. Loss of body (axillary and pubic) hair, reduced need for shaving; **OR**
E. Very small (especially less than 5 mL) or shrinking testes; **OR**
F. Inability to father children or low/zero sperm count; **OR**
G. Height loss, low trauma fracture, low bone mineral density; **OR**
H. Hot flushes, sweats; **OR**
I. Other less specific signs and symptoms including decreased energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance.

Requests for Testopel (subcutaneous testosterone implants) for **continuation of hormone replacement therapy** may be approved if the following criteria are met:

I. Individual met all diagnostic criteria for initial therapy; **AND**
II. Individual has had serum testosterone level measured in the previous 180 days and the value is below or within therapeutic range; **AND**
III. Individual has obtained clinical benefits as noted by symptom improvement.

Requests for Testopel (subcutaneous testosterone implants) **for delayed puberty** may be approved if the following criteria are met:

I. Individual is a male 14 years of age or older; **AND**
II. Individual is using hormone to stimulate puberty; **AND**
III. Individual has few to no signs of puberty.

Requests for Testopel (subcutaneous testosterone implants) **for transgender individuals** may be approved if the following criteria are met:

I. Individual is 16 years of age or older; **AND**
II. Individual has a diagnosis of gender dysphoria/incongruence or gender identity disorder; **AND**
III. The goal of treatment is female-to-male gender reassignment.

Requests for Testopel (subcutaneous testosterone implants) may **not** be approved for the following criteria:

I. Hormone replacement therapy (HRT) for female menopause; **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

II. Delayed puberty in females.

***Estrogen and estrogen containing combination subcutaneous implanted agents**

Requests for estrogen and estrogen containing combination subcutaneous implanted agents will not be approved. These agents are not FDA approved.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

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5. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2018; 103(5): 1715-1744. Available at: https://academic.oup.com/jcem/article/103/5/1715/4939465. Accessed on June 8, 2018.
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7. Hembree WC. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. The journal of clinical endocrinology and metabolism. 2009-09;94:3132-3154.
8. Coleman E, Bockting W, Botzer M, et al. World Professional for Transgender Health (WPATH). Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. Int J Transgen. 2012; 13:165-232. Available at: http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1351&pk_association_webpage=4655.
9. Wang C, Nieschlag E, Swerdloff R, et al. International Society for the Study of Aging Male, the International Society of Andrology, the European Association of Urology, the European Academy of Andrology, and the American Society of Andrology (ISSAM/ISA/EAU/EAA/ASA). Investigation, treatment, and monitoring of late-onset hypogonadism in males: recommendations. Eur Urol. 2009; 55(1):121-130.