Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Testopel (testosterone pellets)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Testopel (testosterone pellets) for subcutaneous implantation

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**
   B. Decreased spontaneous erections; **OR**
   C. Breast discomfort/gynecomastia; **OR**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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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**
II. Delayed puberty in females.

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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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.
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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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