curative

Male Hypogonadism Prior Authorization

Drug(s) Applied:	clomiphene*

*Note: Male infertility is considered an excluded benefit. Female infertility may be covered under an additional fertility rider (see Infertility Prior Authorization).

Criteria:

Drug(s) Applied will be approved when the following criteria are met:

I. Initial Therapy Criteria

A. Male hypogonadism as indicated by chart notes within past 180 days

1. ONE of the following:
   a) Two pre-treatment early morning (between 7-10am) serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L), taken on separate days (document lab value and date for both levels))
   b) History of bilateral orchiectomy or congenital anorchia **and**
2. Documentation of at least ONE of the following signs/symptoms:
   a) Osteopenia or osteoporosis
   b) Decreased libido or erectile dysfunction
   c) Depression
   d) Reduced energy or endurance
   e) Fatigue
   f) Impaired memory, poor concentration
   g) Irritability **and**
3. Patient has tried and failed an adequate trial of testosterone cypionate, testosterone enanthanate, or testosterone gel or has a contraindication to testosterone products

Approval Duration: 6 months on Tier 2

II. Continued Therapy Criteria

A. Male hypogonadism as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Documented clinical benefit since starting the requested agent (i.e., reduction in signs/symptoms) **and**
3. Labs confirming ONE of the following:
   a) If on clomiphene therapy for less than one year, follow-up total serum testosterone level drawn within the past 6 months (any time of day) is within the normal physiological range of 450-600 ng/dL, or if outside of

normal male limits, provider is adjusting the dose

b) If on clomiphene therapy for one year or more, follow up total serum testosterone level drawn within the past 12 months (any time of day) is within the normal physiological range of 450-600 ng/dL, or if outside of normal male limits, provider is adjusting the dose **and**

4. If total testosterone levels are within normal levels and signs/symptoms of hypogonadism have not improved, documentation that provider has assessed cessation of clomiphene therapy and has determined continuation is appropriate

Approval Duration: 12 months on Tier 2

References:

1. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and Management of Testosterone Deficiency: AUA Guideline. American Urological Association Education and Research, Inc. Journal of Urology Vol. 200, 423-432. August 2018. Link.
2. European Association of Urology (EAU) Sexual and Reproductive Health Guidelines. 3. Male Hypogonadism. Edn. presented at the EAU Annual Congress London 2026. ISBN 978-94-92671-32-5. Link.

Policy Owned by: Curative PBM team