1. **Background:**

   The body produces two types of gonadotropins, follicle-stimulating hormone (FSH) and luteinizing hormone (LH), both of which play a role in fertility and human reproduction. After they are produced by the pituitary gland, gonadotropins trigger production of other sex hormones which then promote production of egg and sperm. Gonadotropins include hMG (human menopausal gonadotropin –Menopur and Repronex) and follicle stimulating hormone. Gonadotropins are used in the treatment of infertility, a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse or therapeutic donor insemination.1,2

   Menopur (menotropins) is indicated for the development of multiple follicles and pregnancy in ovulatory women participating in an assisted reproductive technology (ART) program.3 hMG is used for the treatment of ovulation induction in women with ovulatory dysfunction including polycystic ovary syndrome (PCOS) who failed on clomiphene as well as for ovulation induction in the setting of hypogonadotropic hypogonadism. hMG is also used for induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.4−13

   The clinically appropriate dosing for hMG agents when used in an ART cycle without an FSH product is 450 IU/day or less for not more than 14 days of treatment. When used as part of a mixed stimulation protocol (hMG + FSH) or when used alone for ovulation induction or controlled ovarian stimulation the clinically appropriate maximum dosing for hMG agents is 150 IU/day. Exceeding this daily dose and duration of treatment has not been proven to be efficacious in terms of pregnancy outcome.9,13

2. **Coverage Criteria:**

   **A. Controlled Ovarian Stimulation**

   1. **Menopur** will be approved based on **all** of the following criteria*†:

      a. Diagnosis of infertility

      -AND-

      b. For the development of multiple follicles (controlled ovarian stimulation)

      -AND-
c. **One** of the following:

(1) **Both** of the following:

   (a) **One** of the following exists:

      i. Diminished ovarian reserve
      ii. Endometriosis
      iii. Male factor infertility
      iv. Tubal factor infertility
      v. Unexplained infertility
      vi. Uterine infertility
      vii. Ovulatory dysfunction
      viii. Recurrent pregnancy loss
      ix. Failure to achieve conception with other treatment modalities

      **-AND-**

      (b) Will be used in conjunction with assisted reproductive technology (ART)

      **-OR-**

   (2) **Both** of the following:

      (a) **One** of the following exists:

      i. Diminished ovarian reserve
      ii. Mild to moderate male factor infertility
      iii. Minimal to mild endometriosis
      iv. Unilateral tubal factor infertility
      v. Unexplained infertility

      **-AND-**

      (b) Will be used in conjunction with intrauterine insemination (IUI)

**Authorization will be issued for 2 months.**

B. **Ovulation Induction (Off-Label)**

1. **Menopur** will be approved based on **all** of the following criteria*†:

   a. Diagnosis of ovulatory dysfunction

      **-AND-**

   b. **One** of the following exists:

      (1) Anovulation
      (2) Oligo-ovulation
(3) Amenorrhea

-AND-

c. Other specific causative factors (e.g., thyroid disease, hyperprolactinemia) have been excluded or treated

-AND-

d. Infertility is not due to primary ovarian failure

-AND-

e. For induction of ovulation

Authorization will be issued for 2 months.  

C. Hypogonadotropic Hypogonadism (Off-Label)

1. Menopur will be approved based on all of the following criteria*‡:

   a. One of the following:

      (1) Diagnosis of primary hypogonadotropic hypogonadism

          -OR-

      (2) Diagnosis of secondary hypogonadotropic hypogonadism

          -AND-

   b. For induction of spermatogenesis

          -AND-

   c. Infertility is not due to primary testicular failure

Authorization will be issued for 2 months.  

3. Additional Clinical Programs:

   Supply limits may be in place.

*Infertility is typically excluded from coverage for UnitedHealthcare. Please refer to member’s specific benefits for coverage determination.

‡ OptumHealth review only: Please refer to the Clinical Policy on Human Menopausal Gonadotropin (hMG) Used in the Treatment of Infertility for state-specific requirements that may apply.
5 OptumHealth review only: Subsequent authorizations will be reviewed according to the Infertility Clinical Performance Guideline.

4. References:
<table>
<thead>
<tr>
<th>Program</th>
<th>Change Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/2014</td>
<td>Separated Gonadotropin Notification into individual documents. Removed Repronex because it has been discontinued by the manufacturer. Revised criteria for controlled ovarian stimulation and ovulation induction. Updated background and references.</td>
</tr>
<tr>
<td>5/2015</td>
<td>Added Repronex to program since still being manufactured. Minor change to criteria. Updated background and references.</td>
</tr>
<tr>
<td>5/2016</td>
<td>Annual review. Updated criteria for controlled ovarian stimulation. Updated background and references.</td>
</tr>
<tr>
<td>5/2017</td>
<td>Annual review. Removed Repronex because it has been discontinued by the manufacturer. Updated background and references.</td>
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