VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

REPRONEX; MENOPUR (Menotropins)

Effective Date: 7/28/05
Date Developed: 7/14/05 by C. Wilhelmy MD
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Menotropins is a purified combination of follicle stimulating hormone (FSH) and luteinizing hormone (LH) extracted from the urine of postmenopausal women. Treatment provides ovarian follicular growth and maturation in females who do not have primary ovarian failure. Also stimulates spermatogenesis in males (off-label use)

Pre-Authorization Criteria:

For multiple follicle development and pregnancy in ovulatory women as part of an assisted reproductive technology cycle.

Ovulation Induction (Indicated for patients with oligoanovulation):

Repronex: 150 IU IM/SC for the first 5 days of treatment; adjustments not to be made more frequently than every 2 days; not to exceed 75-150 IU per adjustment (not to exceed 450 IU/dose); not to exceed 12 days of therapy

If patient's response satisfactory, administer 5000-10,000 units of hCG one day following the last dose of menotropins

Do not administer hCG dose if serum estradiol >2000 pg/mL, if ovaries abnormally large, or abdominal pain occurs; patient should also refrain from intercourse

May repeat therapy if follicular development inadequate or pregnancy does not occur

Assisted Reproductive Technology (ART):

Menopur
-Begin on cycle day 2 or 3
-Initial dose for women who have received a GnRH agonist for pituitary suppression is 225 IU SC qDay
-May be coadministered with urofollitropin (Bravelle), and the total initial dose when the

products are combined should not exceed 225 IU (ie, menotropins 150 IU and urofollitropin 75 IU OR menotropins 75 IU and urofollitropin 150 IU)
-Therapy should not exceed 20 days
-Consider adjusting the dose after 5 days based on ovarian response, as determined by ultrasound evaluation of follicular growth and serum estradiol levels
-Do not make additional dosage adjustments more frequently than q2days or by >150 IU at each adjustment
-Continue treatment until adequate follicular development is evident, and then administer hCG Withhold hCG in cases where the ovarian monitoring suggests an increased risk of ovarian hyperstimulation syndrome on the last day of menotropin therapy
-Do not administer daily doses of menotropins or menotropins in combination with urofollitropin that exceed 450 IU

Repronex
-225 units SC in patients that have received GnRH agonist for pituitary suppression; adjustments not to be made more frequently than every 2 days; not to exceed 75-150 IU per adjustment (not to exceed 450 IU/dose); not to exceed 12 days of therapy
-If patient's response satisfactory, administer 5000-10,000 IU hCG one day following the last dose of menotropins
-Do not administer hCG dose if serum estradiol >2000 pg/mL, if ovaries abnormally large, or abdominal pain occurs; patient should also refrain from intercourse
-May repeat therapy if follicular development inadequate or pregnancy does not occur

NOTE: Prior to therapy, preform a complete gynecologic exam and endocrinologic evaluation to diagnose the cause of infertility; exclude the possibility of pregnancy; evaluate the fertility status of the male partner; exclude a diagnosis of primary ovarian failure.

CONTRAINDICATIONS:

Hypersensitivity to menotropins or any component of the formulation; primary ovarian failure as indicated by a high follicle-stimulating hormone (FSH) level; uncontrolled thyroid and adrenal dysfunction; abnormal bleeding of undetermined origin; intracranial lesion (i.e., pituitary tumor); ovarian cyst or enlargement not due to polycystic ovary syndrome; infertility due to any cause other than anovulation (except candidates for in vitro fertilization)

Spermatogenesis (Off-Label)**:**

75 IU each of LH and FSH SC/IM 3 times/week for at least 4 months

CONTRAINDICATION: men with normal urinary gonadotropin

PRECAUTIONS: For use by infertility specialists. Advise patient of frequency and potential hazards of multiple pregnancy. May cause ovarian hyperstimulation syndrome (OHSS); if severe, treatment should be discontinued and patient should be hospitalized (may become more severe if pregnancy occurs). Monitor for ovarian enlargement; to minimize the hazard of abnormal ovarian enlargement, use the lowest possible dose. Serious pulmonary conditions (atelectasis, acute respiratory distress syndrome) and arterial thromboembolism have been reported. Safety and efficacy have not been established in renal or hepatic impairment, or in pediatric and geriatric patients. Multiple ovulations resulting in plural gestations have been reported. Ectopic pregnancy and congenital abnormalities have been reported.

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2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Replaced definition of Repronex with Menopur. Modified preauthorization criteria, dosing and contraindication sections