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Infertility

Clinical Policy Bulletins | Medical Clinical Policy Bulletins

Number: 0327

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Note: This policy has updates that may not be in effect for certain plans until plan renewal; please check plan documents.

Policy History

Last Review

11/25/2024

Effective: 05/20/1999

Next Review: 07/24/2025

Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes

Brand Selection for Medically Necessary Indications for Commercial Medical Plans

Follitropins

As defined in Aetna commercial policies, health care services are not medically necessary when they are more costly than alternative services that are at least as likely to produce equivalent therapeutic or diagnostic results. Follistim AQ (follitropin beta) is more costly to Aetna than other follicle-stimulating hormone (FSH) products. There is a lack of reliable evidence that Follistim AQ is superior to other lower cost FSH products for medically necessary indications. Therefore, Aetna considers Follistim AQ to be medically necessary only for members who have a contraindication, intolerance, or ineffective response to an adequate one-month trial of the available equivalent alternative Gonal-F (follitropin alfa).

Policy

Scope of Policy

This Clinical Policy Bulletin addresses services for the management of infertility for commercial medical plans. For Medicare criteria, see Medicare Part B Criteria (https://www.aetna.com/health-care-professionals/medicare/part-b-step.html).

The American Society for Reproductive Medicine (ASRM, 2023) has defined infertility as a "disease, condition, or status characterized by the inability to achieve a successful pregnancy based on a patient’s medical, sexual, and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors; or the need for medical intervention, including, but not limited to, the use of donor gametes or donor embryos in order to achieve a successful pregnancy either as an individual or with a partner; or in patients having regular, unprotected intercourse and without any known etiology for either partner suggestive of impaired reproductive ability, evaluation should be initiated at 12

months when the female partner is under 35 years of age and at 6 months when the female partner is 35 years of age or older. Nothing in this definition shall be used to deny or delay treatment to any individual, regardless of relationship status or sexual orientation." Please see below for medical necessity criteria for specific infertility related procedures.

Note: Requires Precertification:

Precertification of Cetrotide (cetrorelix acetate), ganirelix acetate, Follistim AQ (follitropin beta), Gonal-F (follitropin alfa), Menopur (menotropins), Novarel (chorionic gonadotropin), Pregnyl (chorionic gonadotropin), Ovidrel (choriogonadotropin alfa), and chorionic gonadotropin is required of all Aetna participating providers and members in applicable plan designs. For precertification, call (866) 782-2779 or fax (860) 754-2515. For Statement of Medical Necessity (SMN) precertification forms, see Specialty Pharmacy Precertification (https://www.aetna.com/health-care-professionals/health-care-professional-forms.html).

Note: Medical/Pharmacy Benefit Alignment of Coverage for Infertility Drugs and Procedures:

Medical necessity review of infertility drugs by Aetna Specialty Pharmacy Guideline Management may be bypassed for infertility ART drugs that are for use with infertility medical procedures if the infertility procedure has been approved for coverage under the member's Aetna medical benefit plan. During precertification, a medical authorization number and confirmation of the approval of the infertility procedures will be required to bypass medical necessity review by Specialty Pharmacy Guideline Management. **Note:** Some plans may require medical necessity review of all infertility drugs by Aetna Specialty Guideline Management. Members of these plans must undergo Specialty Pharmacy Guideline Management medical necessity review of all infertility drugs regardless of whether the drugs are for use with approved infertility medical procedures.

Notes:

1. For purposes of this entire policy, coverage is subject to the terms and conditions of the member's benefit plan. Coverage may vary due to state mandates and plan customization; please check plan documents.
2. For plans with an Advanced Reproductive Technology (ART) benefit (please check benefit plan descriptions), less invasive therapeutic approaches should be attempted prior to undertaking more invasive procedures, as directed by an appropriate, licensed medical specialist. The medical necessity criteria in the Advanced Reproductive Technology section below are met for persons who are unable to conceive after an appropriate trial of egg-sperm contact. For women under 35 years of age, an appropriate trial of egg-sperm contact requires 12 months of regular intravaginal inseminations or 4 cycles of timed intrauterine or intracervical inseminations, documented in the medical record. For women 35 years of age and older, an appropriate trial of egg-sperm contact requires 6 months of regular intravaginal inseminations or 3 cycles of timed intrauterine or intracervical insemination, documented in the medical record. This requirement applies to all individuals regardless of sexual orientation or the availability of a reproductive partner. For IVF procedures under the ART benefit, these requirements for a trial of egg-sperm contact are waived for persons for whom intravaginal, intrauterine, or intracervical inseminations would not be expected to be effective and IVF procedures are the only effective treatment (see In Vitro Fertilization (IVF) Procedures subsection below.)
3. Most plans exclude coverage of infertility services for persons who have had a previous sterilization procedure, including tubal sterilization and vasectomy, with or without surgical reversal, and for persons who have undergone a hysterectomy. Please check benefit plan descriptions for details. In addition, infertility services for persons who have undergone voluntary sterilization procedures are not covered because such services are the result of an elective procedure intended to prevent conception.
4. Some plans exclude coverage of Assisted Reproductive Technology (ART) using a woman's own eggs for women with poor ovarian reserve. Ovarian reserve is determined by measurement of menstrual cycle day 3 serum follicle-stimulating hormone (FSH) drawn after the normal onset of menstruation, or after

progesterone induced menstruation for women who do not reliably menstruate. For women 39 years of age and older, ovarian responsiveness is determined by measurement of day 3 FSH obtained within the prior 6 months. For women who are less than 40 years of age, the day 3 FSH must be less than 19 mIU/mL in their most recent laboratory test to use their own eggs. For women 40 years of age and older, their unmedicated day 3 FSH must be less than 19 mIU/mL in all prior tests to use their own eggs. Please check benefit plan descriptions.

5. ART services for women 40 years of age and older with natural menopause is not covered because it is not considered medically necessary treatment of disease; natural menopause is not considered a disease. For women 40 years of age and older, their unmedicated day 3 FSH must be less than 19 mIU/mL in all prior tests to document that they are not menopausal and eligible for coverage of ART. Women who are less than 40 years of age who have a day 3 FSH greater than 19 mIU/L are considered to have the disease of premature ovarian failure (also known as premature ovarian insufficiency, primary ovarian insufficiency, or hypergonadotropic hypogonadism). For women with premature ovarian failure, ART (in vitro fertilization) services are considered medically necessary until they reach 45 years of age. Women 40 years of age and older with premature ovarian failure may submit a new unmedicated D3 FSH level to utilize her own oocytes (even if she has had an elevated D3 FSH level above 40 years of age in the past). For women 40 years of and older with premature ovarian failure, the day 3 FSH must be less than 19 mIU/mL in their most recent laboratory test to use their own eggs. Please check benefit plan descriptions.

I. **Medical Necessity**

A. *Females: Basic Infertility Services*

The following services are considered medically necessary:

1. History and Physical Examination

Basal body temperature;

2. Laboratory Studies

    a. Anti-adrenal antibodies for apparently spontaneous primary ovarian insufficiency (premature ovarian failure);
    b. Anti-sperm antibodies (e.g., immunobead or mixed antiglobulin method);
    c. Chlamydia trachomatis screening (see CPB 0433 - Chlamydia Trachomatis - Screening and Diagnosis (../400_499/0433.html));
    d. Fasting and 2 hours post 75 gram glucose challenge levels;
    e. Lipid panel (total cholesterol, HDL cholesterol, triglycerides);
    f. Post-coital testing (PCT) (Simms-Huhner test) of cervical mucus;
    g. Rubella serology;
    h. Testing for viral status (HIV, hepatitis B, hepatitis C);
    i. Serum hormone levels:

        i. Androgens (testosterone, androstenedione, dehydroepiandrosterone sulfate (DHEA-S) if there is evidence of hyperandrogenism (e.g., hirsuitism, acne, signs of virilization) or ovulatory dysfunction;
        ii. Anti-mullerian hormone (AMH), for the following indications:

            a. assessing menopausal status, including premature ovarian failure;
            b. assessing ovarian status, including ovarian reserve and ovarian responsiveness, as part of an evaluation for infertility and assisted reproduction protocols such as in vitro fertilization;

        iii. Gonadotropins (serum follicle-stimulating hormone [FSH], luteinizing hormone [LH]) for women with irregular menstrual cycles (see Appendixfor medical necessity limitations) or age-related ovulatory

dysfunction. **Note**: Aetna considers urinary FSH testing to be experimental, investigational, or unproven. Serum, not urinary, FSH is the standard of care for determination of menopausal status (AACE, 1999; NAMS, 2000; SOGC, 2002);

iv. Human chorionic gonadotrophin (hCG) (see Appendix for medical necessity limitations);

v. Prolactin for women with an ovulatory disorder, galactorrhea, or a pituitary tumor;

vi. Progestins (progesterone, 17-hydroxyprogesterone) (see Appendix for medical necessity limitations);

vii. Estrogens (estradiol) (see Appendix for medical necessity limitations);

viii. Thyroid stimulating hormone (TSH) for women with symptoms of thyroid disease;

ix. Adrenocortitrophic hormone (ACTH) for ruling out Cushing's syndrome or Addison's disease in women who are amenorrheic;

x. Clomiphene citrate challenge test;

j. Karyotype testing for couples with recurrent pregnancy loss (2 or more consecutive spontaneous abortions) (see CPB 0348 - Recurrent Pregnancy Loss (0348.html));

3. Artificial Insemination(s) (intrauterine, intracervical, or intravaginal)

Note: Some Aetna benefit plans may exclude coverage of artificial insemination (AI). For Aetna benefit plans that cover artificial insemination, coverage may be limited to a maximum number of cycles per lifetime. Please check benefit plan descriptions.

4. Diagnostic Procedures

The following diagnostic procedures are considered medically necessary:

a. CT or MR imaging of sella turcica is considered medically necessary if prolactin is elevated;

b. Endometrial biopsy;

c. Hysterosalpingography (hysterosalpingogram [HSG]) or hysterosalpingo-contrast-ultrasonography (HyCoSy) to screen for tubal occlusion;
The following are considered experimental, investigational, or unproven to screen for tubal occlusion (not an all-inclusive list) because of a lack of reliable evidence of effectiveness:

   i. Sonohysterosalpingography or saline hysterosalpingography (e.g., Femvue);
   ii. Hysterosalpingo-foam sonography (HyFoSy) (e.g. ExEm Foam);

d. Hysteroscopy, salpingoscopy (falloscopy), hydrotubation where clinically indicated;
e. Laparoscopy and chromotubation (contrast dye) to assess tubal and other pelvic pathology, and to follow-up on hysterosalpingography abnormalities;
f. Sonohysterography to evaluate the uterus;
g. Ultrasound (e.g., ovarian, transvaginal, pelvic) (see Appendix for medical necessity limitations);
h. Monitoring of ovarian response to ovulatory stimulants:

   i. Estradiol (see Appendix for medical necessity limitations);
   ii. FSH (see Appendix for medical necessity limitations);
   iii. hCG quantitative (see Appendix for medical necessity limitations);
   iv. LH assay (see Appendix for medical necessity limitations);
   v. Progesterone (see Appendix for medical necessity limitations);
   vi. Serial ovarian ultrasounds are considered medically necessary for cycle monitoring (see Appendix for medical necessity limitations);

5. Non-Surgical Treatments

The following non-surgical treatments are considered medically necessary:

a. Aromatase inhibitors (e.g., anastrozole [Arimidex], exemestane [Aromasin], and letrozole [Femara]);
b. Corticosteroids (e.g., dexamethasone, prednisone);
c. Estrogens (e.g., estrone and conjugated estrogens [Premarin]);
d. Hepatitis B vaccination of partners of people with hepatitis B;
e. Lutropin alfa (Luveris) for use in combination with human FSH to stimulate follicular development in infertile hypo-gonadotropic hypo-gonadal women or in women with a profound LH deficiency defined as LH less than 1.2 International Units/L;
f. Metformin (Glucophage) for women with WHO Group II anovulatory disorders such as polycystic ovarian syndrome;
g. Progestins (oral, topical gel (8 % progesterone) (Crinone 8 %, Prochieve 8 %) or intramuscular progestins and progesterone vaginal suppositories (Endometrin), see CPB 0510 - Progestins (../500_599/0510.html));
h. Prolactin inhibitors (bromocriptine (Parlodel), cabergoline (Dostinex), peroglide (Permax)) for women with ovulatory disorders due to hyperprolactinemia;
i. Rubella vaccination of women susceptible to rubella;
j. Tamoxifen (Novaldex) or oral clomiphene citrate (Clomid, Serophene) for ovulation induction;

Note: The medications listed above may not be covered for members without pharmacy benefit plans; in addition, some pharmacy benefit plans may exclude or limit coverage of some or all of these medications. Please check benefit plan descriptions for details.

6. Infertility Surgery

The following are considered medically necessary:

a. Hysteroscopic adhesiolysis for women with amenorrhea who are found to have intrauterine adhesions;
b. Hysteroscopic or fluoroscopic tubal cannulation (salpingostomy, fimbrioplasty), selective salpingography

plus tubal catheterization, or transcervical balloon tuboplasty for women with proximal tubal obstruction (see CPB 0347 - Transcervical Balloon Tuboplasty (0347.html));

c. Laparoscopic cystectomy for women with ovarian endometriomas;
d. Laparoscopy for treatment of pelvic pathology;
e. Open or laparoscopic resection, vaporization, or fulguration of endometriosis implants plus adhesiolysis in women with endometriosis;
f. Ovarian wedge resection or ovarian drilling for women with WHO Group II ovulation disorders such as polycystic ovarian syndrome who have not responded to clomiphene citrate;
g. Removal of myomas, uterine septa, cysts, ovarian tumors, and polyps;
h. Surgical tubal reconstruction (unilateral or bilateral tubal microsurgery, laparoscopic tubal surgery, tuboplasty and tubal anastomosis) for women with mid or distal tubal occlusion and for women with proximal tubal disease where tubal cannulation has failed or where severe proximal tubal disease precludes the likelihood of successful cannulation;
i. Tubal ligation (salpingectomy) for women with hydrosalpinges who are contemplating in vitro fertilization, as this has been demonstrated to improve the chance of a live birth before in-vitro fertilization treatment;
j. Cervicectomy/trachelectomy is an acceptable alternative to hysterectomy for treatment of early stage (IA2 or small IB1) cervical adenocarcinoma in women who wish to preserve their fertility.

B. *Male Infertility*

The following services are considered medically necessary:

1. History and Physical Examination
2. Laboratory Studies

a. Anti-sperm antibodies (e.g., immunobead or mixed antiglobulin method);
b. Cultures:

i. Prostatic secretion;
ii. Semen;
iii. Urine;

c. Serum hormone levels:

i. 17-hydroxyprogesterone;
ii. Adrenal cortical stimulating hormone (ACTH);
iii. Androgens (testosterone, free testosterone) - if initial testosterone level is low, a repeat measurement of total and free testosterone as well as serum luteinizing hormone (LH) and prolactin levels is medically necessary;
iv. Estrogens (e.g., estradiol, estrone);
v. Gonadotropins (FSH, LH);
vi. Growth hormone (GH);
vii. Prolactin for men with reduced sperm counts, galactorrhea, or pituitary tumors;
viii. Sex hormone binding globulin (SHGB) for men with signs and symptoms of hypogonadism and low normal testosterone levels. (SHGB is not indicated in the routine evaluation of male infertility);
ix. Thyroid stimulating hormone (TSH) for men with symptoms of thyroid disease;

d. Semen analysis - Semen analysis (volume, pH, liquefaction time, sperm concentration, total sperm number, motility (forward progression), motile sperm per ejaculate, vitality, round cell differentiation (white cells versus germinal), morphology, viscosity, agglutination) is considered medically necessary for the evaluation of infertility in men. Because of the marked inherent variability of semen analyses, an abnormal

result should be confirmed by at least one additional sample collected one or more weeks after the first sample;

i. For men with abnormal semen analysis exposed to gonadotoxins, up to 4 semen analyses are considered medically necessary;
ii. For men with a normal initial semen analysis, a repeat semen analysis is considered medically necessary if there is no pregnancy 4 months after the initial normal semen analysis;
iii. If the result of the first semen analysis is abnormal and the man has not been exposed to gonadotoxins, up to 2 repeat confirmatory tests may be considered medically necessary;

e. Semen leukocyte analysis (e.g., Endtz test, immunohistochemical staining);
f. Seminal fructose; Note: Seminal alpha-glucosidase, zinc, citric acid, and acid phosphatase are considered experimental, investigational, or unproven.
g. Blood test for cytogenetic analysis (karyotype and FISH) in men with severe deficits of semen quality or azoospermia (for consideration of intracytoplasmic sperm injection [ICSI]);
h. Y chromosome microdeletion analysis in men with severe deficits of semen quality or azoospermia (for consideration of intracytoplasmic sperm injection [ICSI]); Note: Y chromosome microdeletion analysis is not routinely indicated before ICSI, and is subject to medical necessity review.
i. Post-coital test (PCT) (Simms-Huhner test) of cervical mucus;
j. Sperm penetration assay (zona-free hamster egg penetration test);
k. Karyotyping for persons with recurrent pregnancy loss (defined as 2 or more consecutive spontaneous abortions) (See CPB 0348 - Recurrent Pregnancy Loss (0348.html)) and for men with severe deficits in semen

quality or nonobstructive azoospermia (for consideration of intracytoplasmic sperm injection [ICSI]);

l. Testing for viral status (HIV, hepatitis B, hepatitis C);

m. Genetic testing of CFTR mutations for a man and his female partner if the man has congenital absence of the vas deferens (CAVD);

3. Diagnostic procedures

a. CT or MR imaging of sella turcica if prolactin is elevated;

b. Scrotal exploration;

c. Scrotal (testicular) ultrasound (See CPB 0532 - Scrotal Ultrasonography (../500_599/0532.html));

d. Testicular biopsy;

e. Transrectal ultrasound (See CPB 0001 - Transrectal Ultrasound (../1_99/0001.html));

f. Vasography;

g. Venography;

4. Treatments

a. Endocrine Management

i. Androgens (testosterone) for persons with documented androgen deficiency;

ii. Anti-estrogens (tamoxifen (Nolvadex)) for men with elevated estrogen levels;

iii. Clomiphene (Clomid, Serophene);

iv. Corticosteroids (e.g., dexamethasone, prednisone);

v. Prolactin inhibitors (bromocriptine (Parlodel), cabergoline (Dostinex)) for persons with hyperprolactinemia;

vi. Thyroid hormone replacement for men with thyroid deficiency;

b. Injectable Endocrine Management

i. Gonadotropin releasing hormone analogs and antagonists

For gonadotropin-releasing hormone analogs and antagonists (GnRH; luteinizing hormone releasing hormone (LHRH)) see CPB 0501 - Gonadotropin-Releasing Hormone Analogs and Antagonists (../500_599/0501.html);

ii. Gonadotropins

a. Human chorionic gonadotropin (hCG) (e.g., Novarel, Pregnyl, Ovidrel, generic)

i. Criteria for Initial Approval:
Aetna considers hCG medically necessary for the following indications when criteria are met:

a. Hypogonadotropic hypogonadism - for treatment of hypogonadotropic hypogonadism in members who meet *both* of the following criteria:

i. Low pretreatment testosterone levels; *and*
ii. Low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels.

b. Prepubertal cryptorchidism treatment.

Aetna considers all other indications for males as experimental, investigational, or unproven.

ii. Continuation of Therapy:

Aetna considers continuation of hCG therapy medically necessary for all members (including new members) requesting reauthorization who meet all initial authorization criteria.

b. Follitropins (e.g., follitropin alfa [Gonal-f]; follitropin beta [Follistim AQ])

i. Critieria for Initial Approval:
Aetna considers follitropins medically necessary for treatment of hypogonadotropic hypogonadism in members who meet *both* of the following criteria:

a. Low pretreatment testosterone levels; *and*
b. Low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels.

ii. Continuation of Therapy:

Aetna considers continuation of follitropins therapy medically necessary for all members (including new members) requesting reauthorization who meet all initial authorization criteria.

Note: Many plans that otherwise cover infertility treatments exclude coverage for infertility injectable medications. Please check benefit plan descriptions.

c. Antibiotics for men with an identified infection; Note: Intra-prostatic antibiotic injection is considered experimental, investigational, or unproven;
d. Varicocelectomy (spermatic vein ligation) - see CPB 0413 - Varicocele: Selected Treatments (../400_499/0413.html);
e. Spermatocelectomy and hydrocelectomy;
f. Surgical repair of vas deferens: vasovasostomy; Note: Most plans exclude coverage for reversal of sterilization procedures. This would include vasectomy. Please check benefit plan descriptions for details.
g. Surgical correction of epididymal blockage for men with obstructive azoospermia:

i. Epididymectomy;
ii. Epididymovasostomy;
iii. Excision of epididymal tumors and cysts;

iv. Epididymostomy;

h. Transurethral resection of ejaculatory ducts (TURED) for obstruction of ejaculatory ducts;

i. Orchiopexy;

j. Alpha sympathomimetic agents for retrograde ejaculation (e.g., phenylephrine, imipramine);

k. Hepatitis B vaccination of partners of people with hepatitis B;

l. Impotence treatments - see CPB 0007 - Erectile Dysfunction (../1_99/0007.html).

Note: Under most Aetna benefit plans, self-administered prescription medications are covered under the pharmacy benefit. Please check benefit plan descriptions.

C. *Electroejaculation*

Aetna considers electroejaculation medically necessary DME to overcome total anejaculation secondary to neurologic impairment, which most commonly occurs among members with the following conditions:

1. Diabetic neuropathy;
2. Prior retroperitoneal surgery (most commonly retroperitoneal lymphadenectomy as a treatment of testicular cancer);
3. Spinal cord injury.

D. *Donor Insemination*

1. Donor insemination is considered medically necessary for the following indications:

   a. Non-obstructive azoospermia;
   b. Obstructive azoospermia;
   c. Severe deficits in semen quality in couples who do not wish to undergo intracytoplasmic sperm injection (ICSI);
   d. Severe rhesus isoimmunization;
   e. Where there is a high risk of transmitting a genetic disorder in the male partner to the offspring;

f. Where there is a high risk of transmitting an infectious disease (such as HIV) to the partner or offspring.

E. *Advanced Reproductive Technology*

Note: Coverage is limited to plans with an ART benefit; please check benefit plan descriptions.

1. Injectable Medications

See CPB 0020 - Injectable Medications (../1_99/0020.html).

a. Gonadotropin releasing hormone analogs and antagonists

For gonadotropin-releasing hormone analogs and antagoinists (GnRH; luteinizing hormone releasing hormone [LHRH]) (e.g., generic leuprolide acetate injection, leuprolide acetate for depot suspension [Lupron Depot], goserelin [Zoladex], histrelin [Supprelin LA], triptorelin [Trelstar; Triptodur], ganirelix acetate/cetrorelix acetate [Cetrotide]), see CPB 0501 - Gonadotropin-Releasing Hormone Analogs and Antagonists (../500_599/0501.html);

b. Gonadotropins:

i. Human chorionic gonadotropin (hCG) (e.g., Novarel, Pregnyl, Ovidrel, generic)

a. Criteria for Initial Approval

Aetna considers hCG medically necessary for members undergoing ovulation induction or assisted reproductive technology (ART).

Aetna considers all other indications for females as experimental, investigational, or unproven.

b. Continuation of Therapy

Aetna considers continuation of hCG therapy medically necessary for all members (including new members) requesting reauthorization who meet all initial authorization criteria.

ii. Menotropins for injection (Menopur)

a. Criteria for Initial Approval

Aetna considers menotropins for injection medically necessary for follicle stimulation in members undergoing ovulation induction or assisted reproductive technology (ART) who meet *any* of the following criteria:

i. Member has completed three or more previous cycles of clomiphene or letrozole; *or*
ii. Member has a risk factor for poor ovarian response to clomiphene or letrozole; *or*
iii. Member has a contraindication or exclusion to clomiphene or letrozole; *or*
iv. Member is 37 years of age or older.

b. Continuation of Therapy

Aetna considers continuation of menotropin therapy medically necessary for all members (including new members) requesting reauthorization who meet all initial authorization criteria.

iii. Follitropins (e.g., follitropin alfa [Gonal-f]; follitropin beta [Follistim AQ])

a. Criteria for Initial Approval

Aetna considers follitropins medically necessary for the following indications when criteria are met:

Follicle stimulation - for members undergoing ovulation induction or assisted reproductive technology (ART) who meet *any* of the following criteria:

i. Member has completed three or more previous cycles of clomiphene or letrozole; *or*
ii. Member has a risk factor for poor ovarian response to clomiphene or letrozole; *or*
iii. Member has a contraindication or exclusion to clomiphene or letrozole; *or*
iv. Member is 37 years of age or older.

b. Continuation of Therapy

Aetna considers continuation of follitropins therapy medically necessary for all members (including new members) requesting reauthorization who meet all initial authorization criteria.

Note: Many plans exclude coverage for infertility injectable medications; other plans may limit coverage of ovulation induction cycles with menotropins to a maximum number per lifetime. Please check plan documents for details.

Note: Under most Aetna benefit plans, self-administered prescription medications are covered under the pharmacy benefit. Please check benefit plan descriptions.

2. Ovulation Induction

Aetna considers oral or injectable ovulation induction (OI) medically necessary for women 37 years of age or younger who are unable to conceive or produce conception after an appropriate trial of egg-sperm contact. Oral ovulation induction may occur concurrently with the cycles of egg-sperm contact required to establish medical necessity for ART. For women under 35 years of age, an appropriate trial

of egg-sperm contact requires 12 months of regular intravaginal inseminations or 4 cycles of timed intrauterine or intracervical inseminations documented in the medical record. For women 35 years of age and older, an appropriate trial of egg-sperm contact requires 6 months of regular intravaginal inseminations or 3 cycles of timed intrauterine or intracervical insemination documented in the medical record.

3. In Vitro Fertilization (IVF) procedures

Aetna considers the following in vitro fertilization (IVF) procedures medically necessary for persons who meet *any* of the following criteria:

a. Women who have failed to conceive after a trial of ovulation induction:

i. For women 37 years of age or younger, three cycles of oral or injectable ovulation induction (with or without intravaginal, intrauterine, or intracervical inseminations); *or*
ii. For women 38 years of age or older, no trial of ovulation induction is required; *or*

b. Persons for whom intravaginal, intrauterine, or intracervical inseminations would not be expected to be effective and IVF would be expected to be the only effective treatment, including:

i. Men with azoospermia or severe deficits in semen quality or quantity (see Appendix); or
ii. Women with tubal factor infertility:

a. Bilateral tubal disease (e.g., salpingitis isthmica nodosum, tubal obstruction, absence, or hydrosalpinges).
b. Endometriosis stage 3 or 4 (see Appendix).
c. Failure to conceive after pelvic surgery with restoration of normal pelvic anatomy (e.g.,

myomectomy of cavitary-obscuring myomata, resection of intrauterine adhesions or uterine septum, or surgical reconstruction of tubal disease):

i. After regular egg-sperm contact for 6 months if less than 40 years of age;
ii. After regular egg-sperm contact for 3 months if 40 years of age or older.

d. Unilateral hydrosalpinx with failure to conceive:

i. After regular egg-sperm contact for 12 months if less than 40 years of age;
ii. After regular egg-sperm contact for 6 months if 40 years of age or older.

iii. Inadvertent ovarian hyperstimulation (estradiol level was greater than 1,000 pg/ml plus greater than 3 follicles greater than 16 mm or 4 to 8 follicles greater than 14 mm or a larger number of smaller follicles) during preparation for a planned stimulated cycle in women less than 38 years of age.
iv. Women who have had a hysterectomy, or who have a medical contraindication to pregnancy such as severe cardiac disease, or have a medical condition that requires the mother to ingest a fetotoxic agent. **Note:** Some plans limit and/or exclude coverage for gestational surrogacy; please check benefit plan descriptions.

Note on coverage of ART for preimplantation genetic diagnosis (PGD): In-vitro fertilization (IVF) for PGD (i.e., the embryo biopsy) is covered for persons with an ART benefit when medical necessity criteria for PGD are met as set forth in CPB 0358 - Invasive Prenatal Diagnosis of Genetic Diseases (0358.html).

c. IVF with embryo transfer is considered medically necessary when criteria for ART are met. IVF with embryo transfer includes:

i. Embryo transfer (transcervical transfer back to the donor) (including cryopreserved embryo transfer);
ii. Frozen embryo transfer (FET); (Note: It may be considered medically necessary to freeze embryos not transferred during a stimulated IVF treatment cycle, and to transfer the embryos before the next stimulated treatment cycle because this will minimize ovulation induction and egg collection, both of which carry risks for the woman and use more resources. Before proceeding to a fresh ART cycle, previously frozen oocytes must be used (i.e. fertilized and transferred). Similarly, Before proceeding to the next fresh ART cycle, FET using cryopreserved embryos must be used if there are reasonable quality (grade B or its equivalent) cryopreserved embryo(s) available.
iii. Oocyte (egg) insemination in laboratory dish;
iv. Oocyte (egg) retrieval via laparoscope or transvaginal needle aspiration of follicles;
v. Sperm preparation and capacitation;
vi. Intracytoplasmic sperm injection (ICSI) is considered medically necessary for the following:

a. azoospermia or oligospermia (obstructive or non-obstructive);
b. severe deficits in semen quality or quantity (see Appendix);
c. to fertilize frozen oocytes for in vitro fertilization;
d. persons facing iatrogenic infertility due to cancer chemotherapy, cancer radiotherapy, or surgery for trauma; *or*
e. for couples where a previous IVF treatment cycle has resulted in failed or poor (see Appendix) fertilization;

Notes:

ICSI is considered not medically necessary in men whose abnormal sperm quality or quantity had been rectified by varicocelectomy. For use of ICSI in

preimplantation genetic diagnosis, see CPB 0358 - Invasive Prenatal Diagnosis of Genetic Diseases (0358.html).

Physiological, hyaluronan-selected intracytoplasmic sperm injection (PICSI) is a variation of intracytoplasmic sperm injection (ICSI) that uses hyaluronic acid (HA) to select sperm. The PICSI method is considered experimental, investigational, or unproven because of a lack of reliable evidence of effectiveness compared to standard ICSI.

vii. Assisted hatching is considered medically necessary when the plan in the cycle is to transfer the embryos into the uterus and the member meets any of the following criteria:

a. Age is 38 years or older; *or*
b. Multiple (2 or more) failed embryo transfer attempts; *or*
c. Thickened zona pellucida.

Note: Assisted hatching is a process to assist in the implantation of the embryo; unless the cycle involves that transfer of the embryo assisted hatching is considered not medically necessary.

Note on IVF cycles for embryo banking: IVF cycles for the sole purpose of embryo banking (where none of the embryos that are suitable for transfer are used in the current cycle in which they are created, but are frozen for use in a future cycle) is not considered treatment of disease and is not covered.

Note on oocytes used in ART cycles: IVF cycles using either fresh or previously frozen oocytes are considered medically necessary when the ART cycle is considered medically necessary.

4. *Other Assisted Reproductive Technology (ART) Procedures*

a. Gamete intra-fallopian transfer (GIFT) is considered medically necessary as an alternative to IVF for women with female factor infertility. GIFT includes:

   i. Immediate loading of the eggs into a transfer catheter with sperm and insertion into the member's fallopian tube via the same laparoscope (the member must have at least 1 patent fallopian tube for this method to be an effective treatment for infertility)
   ii. Oocyte (egg) retrieval via laparoscope.

   GIFT is considered experimental, investigational, or unproven for person with male factor infertility or unexplained infertility problems because there is insufficient evidence to recommend GIFT over IVF for these indications.

b. Zygote intra-fallopian transfer (ZIFT), tubal embryo transfer (TET), pronuclear stage tubal embryo transfer (PROUST) is considered medically necessary as an alternative to IVF for women with female factor infertility.

   ZIFT is considered experimental, investigational, or unproven for persons with male factor infertility or unexplained infertility problems because there is insufficient evidence to recommend ZIFT over IVF for these indications.

c. Specialized sperm retrieval techniques (including vasal sperm aspiration, microsurgical epididymal sperm aspiration (MESA), percutaneous epididymal sperm aspiration (PESA), electroejaculation, testicular sperm aspiration (TESA), microsurgical testicular sperm extraction (TESE), seminal vesicle sperm aspiration, and sperm recovery from bladder or urine for retrograde ejaculation) is considered medically necessary to overcome anejaculation or azoospermia.

Note: Most plans exclude coverage of infertility services for persons who have undergone sterilization. This would include sperm retrieval for men who have undergone vasectomy. Please check benefit plan descriptions for details.

d. Oocyte donation is considered medically necessary for managing infertility problems associated with the following conditions, when the infertile member is the intended recipient of the resulting embryos:

   i. Bilateral oophorectomy;
   ii. Gonadal dysgenesis including Turner syndrome;
   iii. High-risk of transmitting a genetic disorder from the female partner to the offspring;
   iv. IVF treatment failure
   v. Ovarian failure following chemotherapy or radiotherapy; *or*
   vi. Premature ovarian failure (failure of ovulation in woman younger than 40 years of age) (considered medically necessary until the woman with POF is 45 years of age).

   Note: Many Aetna plans that otherwise cover ART exclude coverage of fees associated with oocyte donation, including recruitment and selection of donors, ovarian stimulation of donors, collection of oocytes from donors, and screening and storage of donor oocytes. Please check benefit plan descriptions for details. Under plans with benefits for ART that have this exclusion, medically necessary ART services are covered only once an embryo is created from the donor egg.

e. Cryopreservation of mature gametes (oocytes or sperm) or embryos is considered medically necessary for use in persons facing iatrogenic infertility due to chemotherapy, pelvic radiotherapy, other gonadotoxic therapies, or ovary or testicle removal for treatment of disease.

Routine use of gamete cryopreservation in lieu of embryo cryopreservation, gamete cryopreservation to circumvent reproductive aging in healthy persons, cryopreservation of immature gametes, and laser-assisted necrotic blastomere removal from cryopreserved embryos are considered experimental, investigational, or unproven.

Note: Some Aetna plans have a specific contractual exclusion of coverage of any charges associated with embryo cryopreservation or storage of cryopreserved embryos. Please check benefit plan descriptions. In addition, cryopreservation of embryos and gametes (other than short-term cryopreservation of embryos that are necessary for contemporaneous use in infertile persons currently under active fertility treatment, or use of cryopreserved embryos or mature gametes in persons facing infertility due to chemotherapy or other gonadotoxic therapies or gonad removal) is not considered treatment of disease and is not covered.

f. Sperm cryopreservation to circumvent reproductive aging in healthy men is considered experimental, investigational, or unproven.

Note: Some Aetna plans have a specific contractual exclusion of coverage of any charges associated with sperm cryopreservation or storage. Please check benefit plan descriptions. In addition, cryopreservation of sperm (other than cryopreserved sperm in men facing infertility due to chemotherapy or other gonadotoxic therapies or gonad removal) is not considered treatment of disease and is not covered.

Note: A cycle of ART defined in the CPB may be any of the following: IVF (with fresh embryos), IVF/frozen embryo transfer, GIFT or ZIFT.

Note on elective single embryo transfer: In order to reduce the number of high-order multiple pregnancies, current guidelines from the American Society for Reproductive Medicine (ASRM, 2009) recommend elective single embryo transfer for women under the age of 35 who have no prior IVF cycles or who have had a previous IVF cycle that was successful in producing a pregnancy (i.e., documentation of fetal heartbeat) and who have excess embryos of sufficient quality to warrant cryopreservation. For women who meet these criteria who elect transfer of a single fresh embryo, Aetna will consider transfer of 1 cryopreserved embryo immediately subsequent to the fresh embryo transfer as part of the same IVF cycle, under plans that limit the number of IVF cycles that are covered. Please check benefit plan descriptions for details.

II. **Experimental, Investigational, or Unproven**

The following are considered experimental, investigational, or unproven for infertility:

- Acupuncture (see CPB 0135 - Acupuncture (../100_199/0135.html))
- Bariatric surgery (see CPB 0157 - Obesity Surgery (../100_199/0157.html));
- Dehydroepiandrosterone (DHEA)
- Direct intra-peritoneal insemination, fallopian tube sperm transfusion, intra-follicular insemination, and the use of sperm precursors (i.e., round or elongated spermatid nuclei, immature sperm)
- Drainage of ovarian cyst
- DuoStim IVF protocol
- Early Embryo Viability Assessment (Eeva) test
- EmbryoGlue
- Evaluation of CYP1A1 rs4646903 T > C genetic variations for risk of male infertility
- Evaluation of *FAS/FASL* genetic variations for risk of male infertility
- Evaluation of telomere length