Clinical Policy Title:	Infertility and fertility preservation
Policy Number:	RxA.40
Drug(s) Applied:	cetrorelix (Cetrotide™), chorionic gonadotropin, human (Novarel®, Pregnyl®), chorionic gonadotropin, recombinant (Ovidrel®), clomiphene (Clomid®), follitropin alfa, recombinant (Gonal-f®, Gonal-f® RFF, Gonal-f® Redi-ject), follitropin beta, recombinant (Follistim® AQ), ganirelix acetate and menotropin (Menopur®)
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Drugs for the purposes of infertility treatment and/or fertility preservation, such as gonadotropins or gonadotropin-releasing hormone (GnRH) antagonists, may require prior authorization.

Drugs			Indications, Female		Indications, Male	
Drug Name	**Brand Name**	**Drug Class**	**OI**	**ART**	**HH**	**Prepubertal Cryptorchidism**
cetrorelix	Cetrotide™	GnRH antagonist	x	x		
chorionic gonadotropin (human)	Novarel® Pregnyl®	Gonadotropin (hCG)	x	x	x	X
chorionic gonadotropin (recombinant)	Ovidrel®	Gonadotropin (hCG)	x	x		
clomiphene	N/A	Selective Estrogen Receptor Modulator (SERM)	x			
follitropin alfa, recombinant	Gonal-f®	Gonadotropin (FSH)	x	x	x	
follitropin alfa, recombinant	Gonal-f® RFF Gonal-f® RFF Redi-ject	Gonadotropin (FHS)	x	x		
urofollitropin	Bravelle®	Gonadotropin (FHS)	x	x		
follitropin beta, recombinant	Follistim® AQ	Gonadotropin (FSH)	x	x	x	
ganirelex acetate	N/A	GnRH antagonist	x	x		
menotropin	Menopur®	Gonadotropin (hMG - FSH and LH)	x	x		

- cetrorelix (Cetrotide™) is indicated for:
  - The inhibition of premature LH surges in women undergoing COH.

- Chorionic gonadotropin (human) is indicated for:
  - Prepubertal cryptorchidism not due to anatomic obstruction.
  - Selected cases of HH secondary to a pituitary deficiency in males.
  - Induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to POI, and who has been appropriately pre-treated with human menotropins.

- chorionic gonadotropin (recombinant) is indicated for:
  - Induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pre-treated with follicle-stimulating hormones (FSH) as part of an ART program such as IVF and embryo transfer.
  - Induction of ovulation and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to POI.

- clomiphene is indicated for:
  - For the treatment of ovulatory dysfunction in women desiring pregnancy.

- follitropin alfa (recombinant) (Gonal-f®) is indicated for:
  - Induction of ovulation and pregnancy in the anovulatory infertile patient in whom the cause of infertility is functional and not due to primary ovarian failure (known as primary ovarian insufficiency; POI).
  - Development of multiple follicles in the ovulatory patient participating in an ART program.
  - Induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism (HH) in whom the cause of infertility is not due to primary testicular failure (i.e. primary hypogonadism).

- follitropin alfa (recombinant) (Gonal-f® RFF and Gonal-f® RFF Redi-ject) is indicated for:
  - Induction of ovulation and pregnancy in oligo-anovulatory women in whom the cause of infertility is functional and not due to POI.
  - Development of multiple follicles in ovulatory women as part of an ART cycle/program.

- rofollitropin (Bravelle®) is indicated for:
  - Induction of ovulation in women who have previously received pituitary suppression.
  - Development of multiple follicles as part of an ART cycle in ovulatory women who have previously received pituitary suppression.

- follitropin beta (recombinant) is indicated for:
  - Induction of ovulation and pregnancy in anovulatory infertile women in whom the cause of infertility is functional and not due to POI.
  - Pregnancy in normal ovulatory women undergoing controlled ovarian stimulation as part of an in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) cycle [ART cycle].
  - Induction of spermatogenesis in men with primary and secondary HH in whom the cause of infertility is not due to primary testicular failure.

- ganirelix is indicated for:
  - Inhibition of premature luteinizing hormone (LH) surges in women undergoing controlled ovarian hyperstimulation (COH).

- menotropin is indicated for:
  - Development of multiple follicles and pregnancy in ovulatory women as part of an assisted reproductive

technology (ART) cycle. *[Includes OI and ART.]*

Dosing Information				
	Infertility, Female		Infertility, Male	
Drug Name	**Dosing Regimen**	**Maximum Dose**	**Dosing Regimen**	**Maximum Dose**
Follicle stimulating agents				
follitropin alfa, recombinant (Gonal-f®, Gonal-f® RFF, Gonal-f® RFF Redi-ject)	Up to 450 SC IU per day	• Doses are individualized. • Duration typically would not exceed one month per reproductive attempt; however, exceptions may apply reproductive attempt; there may be exceptions.	150 to 300 IU SC TIW up to 18 months in combination with hCG at the dose required to maintain normal testosterone levels.	Regimens & maximum doses/durations vary; single agent hCG therapy followed by follitropin/hCG combination therapy may extend up to 24 months or at times longer.
Follitropin beta, recombinant (Follistim® AQ)	Up to 500 IU SC per day		150 to 225 IU SC on BIW/TIW schedules up to 12 months in combination with hCG at the dose required to maintain normal testosterone levels.	
Menotropin (Menopur®)	Up to 450 IU SC per day			
Bravelle® (urofollitropin)	Up to 450 IU IM or SC per day			
Pituitary suppression agents				
cetrorelix (Cetrotide®)	250 mcg SC once daily			
ganirelex acetate	250 mcg SC once daily			
Ovulatory "trigger" agents				
chorionic gonadotropin, recombinant (Ovidrel®)	250 mcg SC once daily	• Doses are individualized. • An agent from this category is typically given once per reproductive attempt.		
chorionic gonadotropin, human (Novarel®, Pregnyl®)	5,000 to 10,000 Units IM once		Infertility due to HH: Dosing may range from 500 to 4,000 USP Units IM on BIW/TIW schedules for up to 12 months to achieve/maintain normal testosterone levels. Prepubertal cryptorchidism: Dosing may range from 500 to 5,000 IM USP Units with varying schedules (e.g., every	Infertility due to HH: Regimens and maximum doses/durations vary; single agent hCG therapy followed by follitropin/hCG combination therapy may extend up to 24 months or at times longer.

			2nd/3rd day, TIW) with prn repeat courses up to 3 months.	Prepubertal cryptorchidism: Regimens and maximum doses vary. Maximum duration: 3 months.
Selective Estrogen Receptor Modulators				
clomiphene (Clomid®)	50mg PO once daily x5 days of each cycle initially	May increase dose to 100mg PO once daily x5 days if ovulation does not occur with initial dose		

Dosage Forms

- cetrorelix (Cetrotide™): Injection: 0.25 mg/vial
- chronic gonadotropin, human: Injection: 10,000 U/vial
- chorionic gonadotropin, human (Novarel®): Injection: 5,000 U/vial, 10,000 U/vial
- chorionic gonadotropin, human (Pregnyl®): Injection: 10,000 U/vial
- chorionic gonadotropin, recombinant (Ovidrel®): Prefilled syringe: 250 mcg/0.5 mL
- clomiphene: Tablet: 50 mg
- follitropin alfa, recombinant (Gonal-f® multi dose vial): Injection: 450 U/vial; 1,050 U/vial
- follitropin alfa, recombinant (Gonal-f® RFF single dose vial): Injection: 75 U/vial
- follitropin alfa, recombinant (Gonal-f® RFF Redi-ject): Prefilled auto-injection device: 300 U/0.5 mL, 450 U/0.75 mL, 900 U/1.5 mL
- follitropin beta, recombinant (Follistim® AQ): Injection cartridge: 175 IU per 0.210 mL, 350 IU per 0.420 mL, 650 IU per 0.780 mL, 975 IU per 1.170 mL
- ganirelex acetate: Prefilled syringe: 250 mcg/0.5 mL
- Menotropin (Menopur®): Injection: 75 U FSH and 75 U LH/vial
- Bravelle: Injection: 75 U FSH/vial

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Infertility and Fertility Preservation, Female (must meet all):

1. One of the following diagnoses (a or b):
   a. Documented diagnosis of infertility and age 18 years of age or older; or
   b. Fertility preservation (embryo or oocyte cryopreservation) secondary to planned gonadotoxic therapy or gonadectomy, and (i or ii):
      i. Age 18 years of age or older and member meets both of the following (a and b):
         a) Member has received counseling (documented); and
         b) Member has executed an informed consent.
      ii. Of reproductive age (peri/postpubertal; off-label use) and member meets both of the following

(a and b):
   a) All consent/assent signees have received counseling (documented); and
   b) Parents(s)/guardian(s) and member have executed informed consents and assents respectively;
2. Prescribed by or in consultation with a reproductive endocrinologist;
3. Product(s) are requested for (a or b):
   a. OI; or
   b. ART and (i or ii):
      i. OI has failed; or
      ii. Member is not a candidate for OI (examples follow):
         a) Undertaking fertility preservation (e.g. embyro or oocyte cryopreservation) secondary to planned gonadotoxic therapy or gonadectomy;
         b) Tubal blockage;
         c) Uterine cavity abnormality;
         d) Severe male factor infertility; or
         e) Diminished ovarian reserve.
4. Member does not have POI.

Approval Duration
Commercial: 30 days or up to specified trial duration if available
Medicaid: 30 days or up to specified trial duration if available

B. Infertility, male (must meet all):
1. Request is for Gonal-f®, Follistim AQ®, Novarel® or Pregnyl®;
2. Diagnosis of infertility due to HH;
3. Prescribed by or in consultation with a reproductive endocrinologist or urologist;
4. Age 18 years of age or older;
5. Product(s) are requested in one of the following ways (a or b):
   a. Novarel® or Pregnyl® as single-agent therapy to increase testosterone to the normal range (400 to 800 ng/dL); or
   b. Gonal-f® or Follistim-AQ® in combination with either Novarel® or Pregnyl® to induce spermatogenesis once serum testosterone is within the normal range;
6. Testosterone therapy is not prescribed concomitantly; and
7. Member does not have primary testicular failure.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

C. Prepubertal Cryptorchidism (undescended testes) (must meet all):
1. Request is for Novarel® or Pregnyl®;
2. Documented diagnosis of prepubertal cryptorchidism;
3. Prescribed by or in consultation with a pediatric specialist in one of the following areas: endocrinology, urology, genetics, surgery;
4. Age 9 years of age or younger;
5. One of the following (a or b):
   a. Member is not a candidate for corrective surgery;
   b. hCG will be used in coordination with surgery.

Approval Duration
Commercial: 3 months

Medicaid: 3 months

II. Continued Therapy Approval

A. Infertility and fertility preservation, Female (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy; and
3. Request is for an OI or ART cycle currently underway.

Approval Duration
Commercial: 30 days or up to specified trial duration if available
Medicaid: 30 days or up to specified trial duration if available
(For additional reproductive attempts please refer to the initial criteria.)

B. Infertility, male (must meet all):

1. Request is for Gonal-f®, Follistim-AQ®, Novarel® or Pregnyl®;
2. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
3. Member is responding positively to therapy;
4. If request is for Novarel® or Pregnyl® (a or b):
   a. Pregnancy has not yet been achieved; or
   b. Pregnancy has been achieved and another pregnancy is being considered;
5. If request is for Gonal-f® or Follistim-AQ® (a and b):
   a. Will be used in combination with Novarel® or Pregnyl®;
   b. Current reproductive attempt has not yet achieved pregnancy (*if pregnancy has been achieved, refer to initial criteria for subsequent Gonal-f® or Follistim® AQ requests*).

Approval Duration
Commercial: 6 months
Medicaid: 6 months

C. Prepubertal Cryptorchidism (undescended testes) (must meet all):

1. Request is for Novarel® or Pregnyl®
2. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
3. Member is responding positively therapy.

Approval Duration
Commercial: 3 months
Medicaid: 3 months
(Treatment for this indication should not exceed a total of 3 months.)

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
ART: assisted reproductive technology
ASCO: American Society of Clinical Oncology
AYA: adolescent and young adult
BIW: twice weekly
COH: controlled ovarian hyperstimulation
FDA: Food and Drug Administration
FSH: follicle-stimulating hormone

GnRH: Gonadotropin-Releasing Hormone
hCG: human chorionic gonadotropin
HH: hypogonadotropic hypogonadism
hMG: human menopausal gonadotropin
ICSI: intracytoplasmic sperm injection
IM: Intramuscularly
IU: International Units
IVF: in vitro fertilization
LH: luteinizing hormone
NCCN: National Comprehensive Cancer Network
OI: Ovulation Induction
PO: by mouth
POI: primary ovarian insufficiency, primary ovarian failure
SERM: Selective Estrogen Receptor Modulator
SC: Subcutaneous/subcutaneously
TIW: three times weekly

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Pregnancy; for additional contraindications, please refer to the product package inserts.

- Boxed Warning(s):
  - None.

APPENDIX D: General Information
Female Infertility and fertility preservation

- ART includes OI; however, OI as notated in the policy criteria refers to non-ART assisted reproduction encompassing fertility medications and intercourse or intrauterine insemination.
- ART includes 1) in vitro fertilization (IVF; most common), 2) intracytoplasmic sperm injection (ICSI), and 3) assisted reproductive hatching. An IVF interval is generally two weeks in length and includes 1) ovarian stimulation by fertility medications, 2) aspiration and fertilization of oocyte(s) in the laboratory ("in vitro"), then 3) transfer of the embryo(s) into the uterine cavity. ART may be preferable to OI in cases of fertility preservation (embryo or oocyte cryopreservation) secondary to planned gonadotoxic therapy or gonadectomy*, tubal blockage or uterine cavity abnormality, severe male factor infertility, or diminished ovarian reserve.
  - *Gonadotoxic therapies or gonadectomy may be undertaken as treatment for cancer as well as treatment for benign conditions, including autoimmune and hematologic conditions such as systemic lupus erythematosus, multiple sclerosis, autoimmune thrombocytopenia, rheumatoid arthritis, Wegener's granulomatosis and Behçet's disease.
- The American Society of Clinical Oncology (ASCO; 2013) and Society for Assisted Reproductive Technology/American Society for Reproductive Medicine (2007) provide guidelines, including around informed consent, that may help inform requests for fertility preservation prior to gonadotoxic medical treatment for females of reproductive age. ASCO recommendations in this regard are listed below (see article for complete list of recommendations). The ASCO recommendations align with the National Comprehensive Cancer

Network (NCCN) recommendations as presented in Adolescent and Young Adult (AYA) Oncology (Version 1.2020):
    - Adult females:
        - Present both embryo and oocyte cryopreservation as established fertility preservation methods.
        - Inform patients that there is insufficient evidence regarding the effectiveness of ovarian suppression (GnRH analogs) as a fertility preservation method, and these agents should not be relied on to preserve fertility.
    - Adult males:
        - Present sperm cryopreservation (sperm banking) as the only established fertility preservation method.
        - Do not recommend hormonal therapy in men; it is not successful in preserving fertility.
    - Female and male children:
        - Use established methods of fertility preservation (semen cryopreservation and oocyte cyropreservation) for postpubertal minor children, with patient assent, if appropriate, and parent or guardian consent.
- Male Infertility
    - Once reproductive attempts are complete, transition to testosterone replacement therapy is an option if needed for long-term treatment.
    - See above section for fertility preservation in males.
- Prepubertal Cryptorchidism
    - Corrective surgery for cryptorchidism (orchidopexy) is considered first-line therapy. Surgery and/or gonadotropin therapy typically would be completed by 24 months of age to avoid potential negative fertility and cancer risk sequelae.
- Fertility Medications
    - Fertility drugs are used together in coordinated, individualized regimens. The regimens in Background section are presented as general guidelines drawn from FDA labels and expert input. Care should be taken not to interrupt a reproductive attempt currently underway.
    - Drugs not listed in the policy that may have roles in female infertility or fertility preservation include GnRH agonists, aromatase inhibitors (e.g., letrozole), dopamine agonists, tamoxifen and clomiphene citrate.
    - mGH has been used off-label for male HH-associated infertility to induce spermatogenesis.

References

1. Menopur Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals; May 2018. Available at: http://www.ferringusa.com/wp-content/uploads/2019/04/Menopur-PI-Rev.-05.2018-20Mar2019.pdf . Accessed Jan 21, 2021.
2. Bravelle Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals; February 2014. Available at: http://www.ferringusa.com/wp-content/uploads/2016/02/BravellePI-2.2014.pdf. Accessed Jan 22, 2021.
3. Gonal-f Multi-Dose Prescribing Information. Rockland, MA: EMD Serono; Dec 2020. Available at: https://www.emdserono.com/us-en/pi/gonal-f-multidose-pi.pdf . Accessed Jan 21, 2021.
4. Gonal-f RFF Prescribing Information. Rockland, MA: EMD Serono; Dec 2020. Available at: https://www.emdserono.com/us-en/pi/gonal-f-rff-75-iu-pi.pdf . Accessed Jan 21, 2021.
5. Gonal-f RFF Redi-ject Prescribing Information. Rockland, MA: EMD Serono; Feb 2020. Available at: https://www.emdserono.com/us-en/pi/gonal-f-rff-redi-ject-pi.pdf . Accessed Jan 22 2021.
6. Follistim AQ Prescribing Information. Ravensburg, Germany: Vetter Pharma-Fertigung GmbH and Co. KG; June 2020. Available at: https://www.merck.com/product/usa/pi_circulars/f/follistim_aq_cartridge/follistim_cartridge_pi.pdf. Accessed Jan 22, 2021.

7. Ganirelix acetate Prescribing Information. Ravensburg, Germany: Vetter Pharma-Fertigung GmbH and Co. KG; October 2020. Available at: https://www.merck.com/product/usa/pi_circulars/g/ganirelix/ganirelix_pi.pdf. Accessed Jan 21, 2021.
8. Cetrotide Prescribing Information. Rockland, MA: EMD Serono; May 2018. Available at: https://www.emdserono.com/us-en/expertise/fertility.html. Accessed Jan 21, 2021.
9. Ovidrel Prescribing Information. Rockland, MA: EMD Serono; June 2018. Available at: https://www.emdserono.com/us-en/expertise/fertility.html. Accessed Jan 21, 2021.
10. Novarel Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals; May 2018. Available at http://www.ferringusa.com/wp-content/uploads/2017/01/NovarelPI-9.2016.pdf. Accessed Jan 21, 2021.
11. Pregnyl Prescribing Information. Halle, Germany: Baxter Oncology GmbH; January 2015. Available at: https://www.merck.com/product/usa/pi_circulars/p/pregnyl/pregnyl_pi.pdf. Accessed on Jan 21, 2021
12. Clomid prescribing information. Sanofi-aventis U.S. LLC, October 2012. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/016131s026lbl.pdf. Accessed on Jan 21, 2021
13. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI; 2020. Accessed with subscription at: http://www.micromedexsolutions.com. Accessed Jan 21, 2021.

Infertility, Female

14. Di Stefano AF, Rusca A, Radicioni MM, et al. Pharmacokinetics and pharmacodynamics of follicle-stimulating hormone in healthy women receiving single and multiple doses of highly purified human menotrophin and urofollitrophin. Clin Drug Investig. 2016 Dec;36(12):10311044. Accessed Jan 21, 2021.
15. McKnight K, McKenzie LJ. Evaluation of infertility, ovulation induction and assisted reproduction. Last updated April 12, 2016. South Dartmouth (MA): MDText.com, Inc. 2000. Available at: https://www.ncbi.nlm.nih.gov/books/NBK279018/. Accessed Jan 22, 2021
16. Practice Committee of the American Society of Reproductive Medicine. Diagnostic evaluation of the infertile female: a committee opinion. Fertil Steril. June 2015; 103(6): e44e50. Accessed Jan 22, 2021.
17. Yasmin E, Davies M, Conway G, et al. British Fertility Society: 'Ovulation induction in WHO Type 1 anovulation: Guidelines for practice' Produced on behalf of the BFS Policy and Practice Committee. Human Fertility. 2013; 16(4): 228-234. https://doi.org/10.3109/14647273.2013.829673. Accessed Jan 22, 2021
18. Carone D, Caropreso C, Vitti A, Chiappetta R. Efficacy of different gonadotropin combinations to support ovulation induction in WHO type I anovulation infertility: clinical evidences of human recombinant FSH/human recombinant LH in a 2:1 ratio and highly purified human menopausal gonadotropin stimulation protocols. J. Endocrinol. Invest. 35: 996-1002, 2012 DOI: 10.3275/8657. Accessed Jan 22, 2021
19. NICE National Institute for Health Care and Excellence. Fertility problems: assessment and treatment. February 20, 2013 (updated 2017). Available at nice.org.uk/guidance/cg156. Accessed Jan 22, 2021
20. Esteves SC, Schertz JC, Verza S Jr, Schneider DT, Zabaglia SFC. A comparison of menotropin, highly-purified menotropin and follitropin alfa in cycles of intracytoplasmic sperm injection. Reprod Biol Endocrinol. 2009 Oct 14;7:111. doi: 10.1186/1477-7827-7-111. Accessed Jan 22, 2021
21. The Practice Committee of the American Society of Reproductive Medicine. Use of exogenous gonadotropins in anovulatory women: a technical bulletin. Fertil Steril, 2008;90:S712. Accessed Jan 22, 2021
22. Practice Committee of American Society for Reproductive Medicine in collaboration with Society for Reproductive Endocrinology and Infertility. Optimizing natural fertility. Fertil Steril. November 2008; 90(5 Suppl):S1-6. doi: 10.1016/j.fertnstert.2008.08.122. Accessed Jan 22, 2021

Fertility Preservation

23. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Adolescent and young adult (AYA) oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aya.pdf. Version 1.2021. Accessed on Jan 22, 2021.

24. Loren AW, Mangu PB, Nohr Beck L et al. Fertility preservation for patients with cancer: American Society of Clinical Oncology Clinical Practice guideline update. Journal of Clinical Oncology. July 1, 2013; 31(19): 2500-11. Accessed Jan 22, 2021
25. Fertility preservation in patients undergoing gonadotoxic therapy or gonadectomy: a committee opinion. Fertil Steril, 2013;100:121423. Accessed Jan 22, 2021
26. Mature oocyte cryopreservation: a guideline. Fertil Steril, 2013; 99(1):37-43. Accessed Jan 22, 2021
27. In vitro maturation: a committee opinion. The Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Fertil Steril 2013;99:6636. Accessed Jan 22, 2021
28. Fertility preservation in patients with non-oncological conditions. Reproductive BioMedicine Online, Vol 16. No 6. 2008 792-800. Jan 22, 2021
29. Practice Committee of the Society for Assisted Reproductive Technology, Practice Committee of the American Society for Reproductive Medicine. Essential elements of informed consent for elective oocyte cryopreservation: a Practice Committee opinion. Fertil Steril. 2007;88(6):1495. Epub 2007 Oct 17. Accessed Jan 22, 2021

Infertility, Male - Hypogonadotropic Hypogonadism

30. Mulhall JP, Trost LW, Brannigan RE et al. Evaluation and Management of Testosterone Deficiency. American Urological Association Education and Research, Inc. 2018. Accessed Jan 22, 2021 https://www.auanet.org/guidelines/testosterone-deficiency. Accessed Jan 22, 2021
31. Boehm U, Bouloux PM, Dattani MT, et al. European Consensus Statement on congenital hypogonadotropic hypogonadism pathogenesis, diagnosis and treatment Nat. Rev. Endocrinol. 11, 547564 (2015); published online 21 July 2015; doi:10.1038/nrendo.2015.112. Accessed Jan 22, 2021
32. Petak SM, Nankin HR, Spark RF, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients—2002 update. Endocrine Practice. November/December 2002; 8(6): 439456. Accessed Jan 22, 2021

Prepubertal Cryptorchidism

33. Kolon TF, Herndon CDA, Baker LA, et al. Evaluation and treatment of cryptorchidism: AUA guideline. J Urol. 2014;192(2):337. Epub 2014 May 20. Accessed Jan 22, 2021
34. Braga LH, Lorenzo AJ, Romao RLP. Canadian Urological Association-Pediatric Urologists of Canada (CUA-PUC) guideline for the diagnosis, management, and followup of cryptorchidism. Can Urol Assoc J 2017;11(7): E251-60. http://dx.doi.org/10.5489/cuaj.4585. Accessed Jan 22, 2021

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established	01/2020	02/07/2020
Policy reviewed & updated.	05/01/2020	05/20/2020
Policy was reviewed: 1. Clinical policy title was updated. 2. Line of Business Policy Applies to was updated to “All lines of business”. 3. Ganirelex acetate: Dose strength updated. 4. Continued therapy criteria II.A.1 was rephrased to “ Member is currently receiving medication that has been authorized by RxAdvance…”. 5. References were reviewed and updated.	01/22/2021	03/09/2021