Clinical Policy: Leuprolide Acetate (Eligard, Lupaneta Pack, Lupron Depot, Lupron Depot-Ped)

Reference Number: CP.PHAR.173
Effective Date: 10.01.16
Last Review Date: 11.19
Line of Business: Commercial, HIM*, HIM-Medical Benefit, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Leuprolide acetate (Eligard®, Lupaneta Pack® [with norethindrone acetate tablets], Lupron Depot®, Lupron Depot-Ped®) is a gonadotropin-releasing hormone (GnRH) receptor agonist.

**For Health Insurance Marketplace (HIM),* *if request is through pharmacy benefit, Lupron Depot-Ped (3-month) 11.25 mg is non-formulary and cannot be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

FDA Approved Indication(s)

Leuprolide acetate is indicated for:

- Palliative treatment of advanced prostate cancer:
  - Leuprolide acetate injection
  - Eligard
  - Lupron Depot (7.5, 22.5, 30, 45)
- Management of endometriosis, including pain relief and reduction of endometriotic lesions:
  - Lupron Depot (3.75, 11.25)
  - Lupaneta Pack (3.75, 11.25)

  Limitation(s) of use: Initial treatment course is limited to 6 months and use is not recommended longer than a total of 12 months due to concerns about adverse impact on bone mineral density.
- Preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata [fibroids] administered concomitantly with iron therapy:
  - Lupron Depot (3.75, 11.25)

  Limitation of use: the recommended treatment is limited to one injection (3 months)
- Treatment of children with central precocious puberty (CPP):
  - Leuprolide acetate
  - Lupron Depot-Ped (7.5, 11.25, 15, 30)

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation® that leuprolide acetate, Eligard, Lupaneta Pack, Lupron Depot, and Lupron Depot-Ped are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prostate Cancer (must meet all)**:**

1. Diagnosis of prostate cancer;
2. Request is for leuprolide acetate injection, Eligard, or Lupron Depot (7.5 mg, 22.5 mg, 30 mg, 45 mg);
3. Prescribed by or in consultation with an oncologist or urologist;
4. Age ≥ 18 years;
5. Request meets one of the following (a, b, or c):*
   a. Leuprolide acetate injection (SC): Dose does not exceed 1 mg per day;
   b. Eligard (SC)/Lupron Depot (IM): Dose does not exceed 7.5 mg per month, 22.5 mg per 3 months, 30 mg per 4 months, 45 mg per 6 months;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Endometriosis (must meet all)**:**

1. Diagnosis of endometriosis;
2. Request is for Lupron Depot/Lupaneta Pack (3.75 mg, 11.25 mg);
3. Prescribed by or in consultation with a gynecologist;
4. Age ≥ 18 years;
5. Endometriosis as a cause of pain is one of the following (a or b):
   a. Surgically confirmed;
   b. Clinically suspected and member has failed a 3-month trial of one of the following agents within the last year or has a documented intolerance or contraindication to the agent (i, ii or iii):
      i. A nonsteroidal anti-inflammatory drug;
      ii. An oral or injectable depot contraceptive;
      iii. A progestin;
6. Dose does not exceed 3.75 mg per month or 11.25 mg per 3 months.

Approval duration: 6 months
Total duration of therapy should not exceed 12 months.

C. Uterine Fibroids (must meet all)**:**

1. Diagnosis of anemia secondary to uterine leiomyomata (fibroids) confirmed by ultrasound;
2. Request is for Lupron Depot (3.75 mg, 11.25 mg);
3. Prescribed by or in consultation with gynecologist;
4. Age ≥ 18 years;
5. Prescribed preoperatively to reduce fibroid size and improve hematologic control;
6. Dose does not exceed 3.75 mg per month, 11.25 mg per 3 months.

Approval duration: 3 months
Total duration of therapy should not exceed 6 months.

D. Central Precocious Puberty (must meet all)**:**

1. Diagnosis of CPP confirmed by all of the following (a, b, and c):

a. Elevated basal luteinizing hormone (LH) level > 0.2 - 0.3 mIU/L (dependent on type of assay used) and/or elevated leuprolide-stimulated LH level > 3.3 - 5 IU/L (dependent on type of assay used);
b. Difference between bone age and chronological age was > 1 year (bone age-chronological age;
c. Age at onset of secondary sex characteristics is < 8 years if female, or < 9 years if male;

2. Request is for one of the following products (a or b):
   a. Leuprolide acetate;
   b. Lupron Depot Ped: 7.5 mg, 11.25 mg, 15 mg, 30 mg;
3. Prescribed by or in consultation with a pediatric endocrinologist;
4. Member meets one of the following age requirements (a or b):
   a. Female: 2 - 11 years;
   b. Male: 2 - 12 years;
5. Dose does not exceed the following (a, b, or c):
   a. Diagnostic use: Leuprolide acetate: 20 mcg/kg or as needed;
   b. Therapeutic use: Leuprolide acetate (SC): Initial: 50 mcg/kg per day; titrate dose upward by 10 mcg/kg per day if down-regulation is not achieved (higher mg/kg doses may be required in younger children).
   c. Therapeutic use: Lupron Depot-Ped (IM): 15 mg per month (1-month formulation) or 30 mg per 3 months (3-month formulation) (dosing is weight-based).

Approval duration:
Commercial/Medicaid – 12 months
HIM – 12 months for leuprolide acetate and Lupron Depot Ped 1.5 mg, 11.25 (1-month), 15 mg, 30 mg (*refer to HIM.PA.103 for Lupron Depot Ped (3-month) 11.25 mg if pharmacy benefit)*

E. Breast and Ovarian Cancer (off-label) (must meet all)**:**
1. Diagnosis of breast or ovarian cancer (including fallopian tube and primary peritoneal cancer);;
2. Request is for one of the following (a or b):
   a. Breast cancer: Lupron Depot 3.75 mg;
   b. Ovarian cancer: Lupron Depot 3.75 mg or 11.25 mg;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Request meets one of the following (a, b, or c):*
   a. Breast or ovarian cancer: Dose does not exceed 3.75 mg per month;
   b. Ovarian cancer: Dose does not exceed 11.25 mg per 3 months;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

F. Gender Dysphoria (off-label) (must meet all)**:**
1. Diagnosis of gender dysphoria;
2. Prescribed by or in consultation with an endocrinologist and an expert in gender dysphoria and transgender medicine (e.g., mental health professional such as psychologist, psychiatrist);
3. Age and pubertal development - meets (a or b):
   a. Member has reached or passed through Tanner Stage 2* and is < 18 years of age;

      **Age ranges approximating Tanner Stage 2 pubertal development extend from 8 to 13 years of age in girls and 9 to 14 years of age in boys.*
   b. Member is ≥ 18 years of age and has failed to achieve physiologic hormone levels with gender-affirming hormonal therapy (e.g., estrogen, testosterone) unless contraindicated or clinically significant adverse effects are experienced;
4. Member demonstrates understanding of expected GnRH analogue treatment outcomes and has given consent for such treatment;
5. If member has a psychiatric comorbidity, member is followed by mental health provider;
6. Psychosocial support will be provided during treatment;
7. Request is not for Lupaneta Pack;
8. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

G. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid and HIM-Medical Benefit.

II. Continued Therapy

A. Prostate Cancer (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving leuprolide acetate injection, Eligard, or Lupron Depot for prostate cancer and has received this medication for at least 30 days;
2. Request is for leuprolide acetate injection, Eligard, or Lupron Depot (7.5 mg, 22.5 mg, 30 mg, 45 mg);
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. Leuprolide acetate injection (SC): New dose does not exceed 1 mg per day;
   b. Eligard (SC)/Lupron Depot (IM): New dose does not exceed 7.5 mg per month, 22.5 mg per 3 months, 30 mg per 4 months, 45 mg per 6 months;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Endometriosis (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Request is for Lupron Depot/Lupaneta Pack (3.75 mg, 11.25 mg);
3. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters: improvement in dysmenorrhea, dyspareunia, pelvic pain/induration/tenderness, or size of endometrial lesions;
4. If request is for a dose increase, new dose does not exceed 3.75 mg per month or 11.25 mg per 3 months.

Approval duration: 6 months
Total duration of therapy should not exceed 12 months.

C. Uterine Fibroids (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Request is for Lupron Depot (3.75 mg, 11.25 mg);
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 3.75 mg per month or 11.25 mg per 3 months.

Approval duration: 3 months
Total duration of therapy should not exceed 6 months.

D. Central Precocious Puberty (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Request is for leuprolide acetate or Lupron Depot-Ped;
3. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters: decreased growth velocity, cessation of menses, softening of breast tissue or testes, arrested pubertal progression;
4. Member meets one of the following age requirements (a or b):
   a. Female: ≤ 11 years;
   b. Male: ≤ 12 years;
5. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. Leuprolide acetate (SC): Initial: 50 mcg/kg per day; titrate dose upward by 10 mcg/kg per day if down-regulation is not achieved (higher mg/kg doses may be required in younger children);
   b. Lupron Depot-Ped (IM): 15 mg per month (1-month formulation) or 30 mg per 3 months (3-month formulation) (dosing is weight-based).

Approval duration:
Commercial/Medicaid – 12 months
HIM – 12 months for leuprolide acetate and Lupron Depot Ped 1.5 mg, 11.25 (1-month), 15 mg, 30 mg (*refer to HIM.PA.103 for Lupron Depot Ped (3-month) 11.25 mg if pharmacy benefit)*

E. Breast and Ovarian Cancer (off-label) (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Lupron Depot for breast cancer or ovarian cancer and has received this medication for at least 30 days;
2. Request is for one of the following (a or b):
   a. Breast cancer: Lupron Depot 3.75 mg;
   b. Ovarian cancer: Lupron Depot 3.75 mg or 11.25 mg;
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. Breast or ovarian cancer: New dose does not exceed 3.75 mg per month;
   b. Ovarian cancer: New dose does not exceed 11.25 mg per 3 months;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

F. Gender Dysphoria (off-label) (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

G. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid and HIM-Medical Benefit.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid and HIM-Medical Benefit or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CPP: central precocious puberty
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, 5th edition
FDA: Food and Drug Administration

GnRH: gonadotropin-releasing hormone
LH: luteinizing hormone
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
NSAIDs*: ibuprofen, naproxen, fenoprofen, ketoprofen, mefenamic acid, meclofenamate, indomethacin, tolmetin, diclofenac, etodolac, diflunisal, meloxicam, piroxicam	Endometriosis Varies – refer to specific prescribing information	Varies – refer to specific prescribing information
Combined oral estrogen-progesterone contraceptives: ethinyl estradiol + (desogestrel, ethynodiol diacetate, drospirenone, etonogestrel, levonorgestrel, norelgestromin, norethindrone, norgestimate, or norgestrel); estradiol valerate + dienogest; mestranol + norethindrone	Endometriosis 1 tablet PO QD (may vary per specific prescribing information)	1 tablet per day (may vary per specific prescribing information)
Progestin-only oral contraceptives: norethindrone	Endometriosis 0.35 mg PO QD	0.35 mg per day
Depot injection progestin contraceptives: medroxyprogesterone acetate	Endometriosis IM: 150 mg per 3 months (every 13 weeks) SC: 104 mg per 3 months (every 12 to 14 weeks)	See regimen

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Examples provided may not be all-inclusive*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to GnRH, GnRH agonist analogs or any of the components of the individual products (all leuprolide products);
  - Pregnancy (all leuprolide products except Eligard);
  - Lupron 3.75 mg/11.25 mg and Lupaneta Pack:
    - Undiagnosed abnormal vaginal bleeding;
    - Breast-feeding;
    - If used with norethindrone acetate:

- Thrombophlebitis, thromboembolic disorders, cerebral apoplexy, or a past history of these conditions;
- Markedly impaired liver function or liver disease;
- Known or suspected carcinoma of the breast.

- Boxed warning(s): None reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Leuprolide acetate injection	Prostate cancer	1 mg SC QD	See regimen
Leuprolide acetate (Lupron Depot 7.5, 22.5, 30, 45)	Prostate cancer	IM - 7.5 mg per month; 22.5 mg per 3 months; 30 mg per 4 months; 45 mg per 6 months	See regimen
Leuprolide acetate (Eligard 7.5, 22.5, 30, 45)	Prostate cancer	SC - 7.5 mg per month; 22.5 mg per 3 months; 30 mg per 4 months; 45 mg per 6 months	See regimen
Leuprolide acetate (Lupron Depot 3.75, 11.25) Leuprolide acetate (Lupaneta Pack 3.75, 11.25)	Endometriosis	IM: 3.75 mg per month; 11.25 mg per 3 months	See regimen
Leuprolide acetate (Lupron Depot 3.75)	Uterine fibroids	IM: 3.75 mg per month, 11.25 mg per 3 months	See regimen
Leuprolide acetate injection	CPP	SC: • Diagnostic: 20 mcg/kg or as needed; • Treatment: Initial: 50 mcg/kg/day; titrate dose upward by 10 mcg/kg/day if down-regulation is not achieved (higher mg/kg doses may be required in younger children).	See regimen
Leuprolide acetate (Lupron Depot-Ped 7.5, 11.25, 15 [1 mo]; 11.25, 30 [3 mo])	CPP	IM monthly: weight-based starting dose: 7.5 mg (≤ 25 kg), 11.25 mg (> 25 to 37.5 kg), 15 mg (> 37.5 kg) (increase as needed to 15 mg per month); 3-month administration: 11.25 mg or 30 mg	See regimen
Leuprolide acetate (Lupron Depot 3.75)	Breast cancer	3.75 mg IM per month	See regimen

Drug Name	Indication	Dosing Regimen	Maximum Dose
Leuprolide acetate (Lupron Depot 3.75, 11.25)	Ovarian cancer	3.75 mg IM per month, 11.25 mg IM per 3 months	See regimen

VI. Product Availability

Drug Name	Availability
Leuprolide acetate injection	Kit: 2.8 mL multi-dose vial (1 mg/0.2 mL)
Leuprolide acetate (Eligard)	Kit: 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month)
Leuprolide acetate and norethindrone tablets (Lupaneta Pack)	Pack: 3.75 mg leuprolide acetate syringe (1 month) with 5 mg norethindrone tablets Pack: 11.25 mg leuprolide acetate syringe (3 month) with 5 mg norethindrone tablets
Leuprolide acetate (Lupron Depot)	Prefilled syringe: 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month)
Leuprolide acetate (Lupron Depot 3.75)	Prefilled syringe: 3.75 mg (1 month)
Leuprolide acetate (Lupron Depot 11.25)	Prefilled syringe: 11.25 mg (3 month)
Leuprolide acetate (Lupron Depot-Ped)	Prefilled syringe: 7.5 mg (1 month), 11.25 mg (1 month), 15 mg (1 month) Prefilled syringe: 11.25 mg (3 month), 30 mg (3 month)

VII. References

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Gender Dysphoria

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Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg
J9217	Leuprolide acetate (for depot suspension), 7.5 mg
J9218	Leuprolide acetate, per 1 mg
J9219	Leuprolide acetate implant, 65 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.118.GnRH Analogs. Prostate cancer – locally confined with radiation therapy; age added 18 or older per PI; max dose added; staging restated per PI Approval period limited to 6 months total with radiation therapy per guidelines Prostate cancer – advanced/palliative; age added 18 or older per PI; max dose added; removed preferencing other than a trial of injectables before receiving implant; staging of advanced prostate cancer restated as stage T3 through T4 or high risk through nodal/metastatic disease per guidelines; added confirmation that treatment intent is palliative if designated in PI; approval period extended to q 12 months Breast cancer – advanced/palliative; age added 18 or older per PI; max dose added; defined advanced as stage IV or recurrent metastatic disease per guidelines; removed requirement for ER/PR+ status as guidelines note status not always clear and that GnRH analogs can be effective in either case; add peri-menopausal status per Zoladex guideline; FDA approved and off-label breast cancer criteria is stated the same based on Zoladex PI and guidelines; added confirmation that treatment intent is palliative as designated in Zoladex PI; approval period; extended to q 12 months Endometriosis - age added 18 or older per PI; max dose added; removed that surgical diagnosis had to be within last year; for clinical diagnosis, restated failure of one three-month trial to analgesics and/or contraceptives per UpToDate; approval period restated per PIs as follows: 6 months total if Zoladex, up to 12 months total for all others per products. Endometrial thinning prior to ablation - age added 18 or older per PI; max dose added	02.16	02.16
Endometriosis: Changed 3 month trial of analgesics and/or hormonal contraceptives to NSAIDS and/or hormonal contraceptives.	05.16	
Per the PI, pregnancy is not a contraindication in cases of advanced breast cancer so it is removed as such in sections I.B and II.B above.	10.16	
Age removed. Formulations added. Off-label NCCN recommended uses added (prostate and breast cancer; doses removed; 3-month injectable requirement removed).	01.17	02.17
Age and dosing added to oncology criteria; age added to gynecology criteria. Positive therapeutic response examples added to oncology and endometriosis criteria. Oncology FDA/NCCN (categories 1 and 2A) indications listed separately.	09.17	11.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Pelvic pain criteria deleted with direction to suspected endometriosis if appropriate. Endometriosis step therapy edited from estrogen/progestin OC to OC or depot contraceptive or progestin. Total approval duration increased from 6 to 12 months. Concomitant iron therapy and specific time period within which surgery must be performed are removed from fibroid criteria. Total approval duration increased from 3 to 6 months. Specialist requirement added for endometriosis, fibroids, CPP. Safety information removed with exception of pregnancy.		
4Q 2018 annual review; policies combined for Centene Medicaid and HIM (HIM.PA.SP51); no significant changes; for oncology, summarized NCCN and FDA-approved uses for improved clarity (limited to diagnosis); specialist involvement in care and continuation of care added; references reviewed and updated.	08.07.18	11.18
Addition of gender dysphoria as off-label use.	07.16.19	08.19
4Q 2019 annual review: added Commercial and HIM-Medical Benefit line of business, added notation that Lupron Depot-Ped (3 month) 11.25 mg strength is non-formulary for HIM; for prostate cancer added urologist specialist option; references reviewed and updated.	08.01.19	11.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.