Medical Policy

Lupron Depot®, Lupron Depot-Ped®, Eligard®, Fensolvi®, Camcevi™	
MEDICAL POLICY NUMBER	MED_Clin_Ops-109
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov *for additional information.*

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for leuprolide acetate, Lupron Depot®, Lupron Depot-Ped®, Eligard®, Fensolvi®, Camcevi™ therapy.

POLICY

Prior Authorization and Medical Review is required.

Length of Authorization

- Endometriosis: Coverage will be provided for 6 months and may be renewed one time only.
- Uterine Leiomyomata (fibroids): Coverage will be provided for 3 months and may NOT be renewed.
- All Other Indications: Coverage will be provided for 12 months and may be renewed.

Medical Policy

Max Units (per dose and over time) [HCPCS Unit]:

Diagnosis	HCPCS	Product(s)	Billable Units	Days Supply
Prostate Cancer	J9217	Lupron Depot 1-Month & Eligard 7.5 mg	1	28
		Lupron Depot 3-Month & Eligard 22.5 mg	3	84
		Lupron Depot 4-Month & Eligard 30 mg	4	112
		Lupron Depot 6-Month & Eligard 45 mg	6	168
Endometriosis; Uterine Fibroids	J1950	Lupron Depot 1-Month 3.75 mg	1	28
		Lupron Depot 3-Month 11.25 mg	3	84
Central Precocious Puberty	J1950/ J1951	Lupron Depot-Ped 7.5 mg	2	28
		Lupron Depot-Ped 11.25 mg	3	28
		Lupron Depot-Ped 15 mg	4	28
		Lupron Depot-Ped 30 mg	8	84
		Fensolvi 45 mg Kit	180	168
Prostate Cancer	J1952	Camcevi 42 mg Kit	(42 mg)	168
Gender Dysphoria	J1950/ J1951	Lupron Depot 1-Month 3.75 mg	1	28
		Lupron Depot 3-Month 11.25 mg	3	84
		Lupron Depot-Ped 11.25 mg	3	28
		Fensolvi 45 mg Kit	180	168

Initial

A. Patient is at least 18 years of age (unless otherwise specified); **AND**

Central Precocious Puberty (CPP) (J1950 and J1951)

A. Patient is less than 13 years of age; **AND**
B. Onset of secondary sexual characteristics earlier than age 8 for females and 9 for males associated with pubertal pituitary gonadotropin activation; **AND**
C. Diagnosis is confirmed by pubertal gonadal sex steroid levels and a pubertal luteinizing hormone (LH) response to stimulation by native growth hormone-releasing hormone (GnRH); **AND**
D. Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; **AND**
E. Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting

tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor); **AND**

F. Requested drug will not be used in combination with growth hormone.

Endometriosis (J1950 only)

A. Documentation patient's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment)

Uterine Leiomyomata (fibroids) (J1950 only)

A. Documentation patient's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment); **AND**
B. Documentation patient is receiving iron therapy.

Prostate Cancer (J9217, J9218, and J1952)

A. Patient has advanced disease

Gender Dysphoria (formerly Gender Identity Disorder) (J1950 and J1951)

A. Patient has a diagnosis of gender dysphoria as confirmed by a qualified mental health professional (MHP)* OR the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) Criteria**; **AND**

B. A qualified MHP* has confirmed all of the following:
   a. Patient has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed); **AND**
   b. Gender dysphoria worsened with the onset of puberty; **AND**
   c. Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment; **AND**
   d. Patient has sufficient mental capacity to give informed consent to this (reversible) treatment; **AND**

C. Patient has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility; **AND**

D. Patient has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process; **AND**

E. A pediatric endocrinologist or other clinician experienced in pubertal assessment has confirmed all of the following:
   a. Agreement in the indication for treatment; **AND**
   b. Puberty has started in the adolescent (e.g., Tanner stage ≥G2/B2); **AND**
   c. There are no medical contraindications to treatment

***Definition of a qualified mental health professional**

- A master's degree or its equivalent in a clinical behavioral science field. This degree or a more advanced one should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should also have documented credentials from the relevant licensing board or equivalent; **AND**

- Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Diseases for diagnostic purposes; **AND**
- Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria; **AND**
- Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria; **AND**
- Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

****DSM-V Criteria for Gender Dysphoria**

- A marked incongruence between one's experienced/expressed gender and natal gender of at least 6mo in duration, as manifested by at least TWO of the following:
  - A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
  - A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
  - A strong desire for the primary and/or secondary sex characteristics of the other gender
  - A strong desire to be of the other gender (or some alternative gender different from one's designated gender)
  - A strong desire to be treated as the other gender (or some alternative gender different from one's designated gender)
  - A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's designated gender); AND
- The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning; AND
- Specify one of the following:
  - The condition exists with a disorder of sex development; OR
  - The condition is post-transitional, in that the individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one sex-related medical procedure or treatment regimen—namely, regular sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in natal males; mastectomy or phalloplasty in natal females).

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: tumor flare, hyperglycemia/diabetes, cardiovascular disease (myocardial infarction, sudden cardiac death, stroke), QT/QTc prolongation, convulsions, etc.; **AND**

Prostate Cancer (J9217 and J1952)

A. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

Central Precocious Puberty (CPP) (J1950 and J1951)

A. Patient is less than 13 years of age; **AND**
B. Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, a decrease in the ratio of bone age to chronological age (BA:CA), and improvement in final height prediction; **AND**
C. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: convulsions, development or worsening of psychiatric symptoms, etc.; **AND**
D. Will not be used in combination with growth hormone.

Gender Dysphoria (J1950 and J1951)

A. Patient has shown a beneficial response to treatment as evidenced by routine monitoring of clinical pubertal development and applicable laboratory parameters.

Endometriosis (J1950 only)

A. Patient has not received a total of 12 months of therapy of a GnRH-agonist (i.e., leuprolide acetate, etc.); **AND**
B. Patient continues to have symptoms of endometriosis or symptoms recur after the initial 6-month course of therapy; **AND**
C. Patient will have bone density assessment prior to retreatment; **AND**
D. Extended GnRH-agonist treatment will be used in combination with norethindrone add-back therapy.

Uterine Leiomyomata (fibroids) (J1950 only)

A. Coverage may NOT be renewed

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. TRIPTODUR (triptorelin) for extended-release injectable suspension, for intramuscular use. Initial U.S. Approval: 2000

CODING

Drug Name	Strength	HCPCS*	NDC
Lupron Depot 1-Month	3.75 mg	J1950	00074-3641-xx
Lupron Depot 1-Month	7.5 mg	J9217	00074-3642-xx
Lupron Depot 3-Month	11.25 mg	J1950	00074-3663-xx
Lupron Depot 3-Month	22.5 mg	J9217	00074-3346-xx
Lupron Depot 4-Month	30 mg	J9217	00074-3683-xx
Lupron Depot 6-Month	45 mg	J9217	00074-3473-xx
Lupron Depot-Ped	7.5 mg	J1950	00074-2108-xx
Lupron Depot-Ped	11.25 mg	J1950	00074-2282-xx
Lupron Depot-Ped 3-Month	11.25 mg	J1950	00074-3779-xx
Lupron Depot-Ped	15 mg	J1950	00074-2440-xx
Lupron Depot-Ped 3-Month	30 mg	J1950	00074-9694-xx
Eligard	7.5 mg	J9217	62935-0753-xx
Eligard	22.5 mg	J9217	62935-0223-xx
Eligard	30 mg	J9217	62935-0303-xx
Eligard	45 mg	J9217	62935-0453-xx
Fensolvi	45 mg	J1951	62935-0153-xx
Camcevi	42 mg	J1592	72851-0042-xx

*J1950: Injection, leuprolide acetate (for depot suspension), per 3.75 mg
*J9217: Leuprolide acetate (for depot suspension), 7.5 mg
*J1951: Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg
*J1952: Leuprolide injectable, camcevi, 1 mg

J1950

ICD-10	ICD-10 Description
D25.0	Submucous leiomyoma of uterus
D25.1	Intramural leiomyoma of uterus
D25.2	Subserosal leiomyoma of uterus
D25.9	Leiomyoma of uterus, unspecified
E30.1	Precocious puberty
E30.8	Other disorders of puberty
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
N80.0	Endometriosis of uterus
N80.1	Endometriosis of ovary
N80.2	Endometriosis of fallopian tube

N80.3	Endometriosis of pelvic peritoneum
N80.4	Endometriosis of rectovaginal septum and vagina
N80.5	Endometriosis of intestine
N80.6	Endometriosis in cutaneous scar
N80.8	Other endometriosis
N80.9	Endometriosis, unspecified

J9217

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

J1951 (Fensolvi only)

ICD-10	ICD-10 Description
E30.1	Precocious puberty
E30.8	Other disorders of puberty
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified

J1952 (Camcevi only)

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

EVIDENCE BASED REFERENCES

1. Lupron Depot GYN 3 Month 11.25 mg [package insert]. North Chicago, IL; Abbvie Inc.; March 2020. Accessed February 2022.
2. Lupron Depot GYN 3.75 mg and 3 Month 11.25 mg [package insert]. North Chicago, IL; Abbvie Inc.; February 2021. Accessed February 2022
3. Lupron Depot-Ped [package insert]. North Chicago, IL; Abbvie Inc.; March 2021. Accessed February 2022.
4. Lupron Depot URO [package insert.]. North Chicago, IL; Abbvie Inc.; March 2019. Accessed February 2022.

5. Eligard [package insert]. Fort Collins, CO; Tolmar Therapeutics, Inc; April 2019. Accessed February 2022.
6. Fensolvi [package insert]. Fort Collins, CO; Tolmar Therapeutics, Inc; May 2020. Accessed February 2022.
7. Camcevi [package insert]. Taipei City, Taiwan; Foresee Pharmaceuticals Co., Ltd.; May 2021. Accessed February 2022.

POLICY HISTORY

Original Effective Date	5/24/2022
Revised Date	March 1, 2023: Adopted by MA UM Committee – no changes made. January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan
P&T Committee Endorsement	5/24/2022