

#### **Part B Prior Authorization Guidelines**

## Camcevi

Camcevi (leuprolide injectable) J1952 Prior Authorization Request Medicare Part B Form

Instructions: \* Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

	Standa	ard Request– (72 Hou	urs)			<b>it Request</b> (ser's life, health c				
	Date Req	uested								
	Requesto	r Clinie	c name:			Phone		/ Fax		
MEMBER INFORMATION										
*Name:			*I[	*ID#:			*DO	B:		
PRESCRIBER INFORMATION										
*Name:			DM	/ID □FNP □DO □NP □PA *Phone:						
*Address:				*Fax:						
DISPENSING PROVIDER / ADMINISTRATION INFORMATION										
*Name: Phone:										
*Address:					Fax:					
PROCEDURE / PRODUCT INFORMATION										
нс	PC Code	Name of Drug		Dos	e (Wt: _	kg Ht:	)	Frequency	End Date if known	
□ Self-administered □ Provider-administered						🗆 Home In	fusion			
Chart notes attached. Other important information:										
Diagnosis: ICD10: Description:										

□ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

New Start or Initial Request: (Clinical documentation required for all requests)							
Prostate cancer, as indicated by 1 or more of the following:							
Intermediate-risk, high-risk, or very high-risk disease, as indicated by 1 or more of the following:							
☐ Intern'l Society of Urological Pathology (ISUP) Grade Group 2 to 5 (Gleason score: 7 to 10)							
Pretreatment PSA of 10 ng/mL (mcg/L) or greater							
Stage T2b/T2c, stage T3a/T3b, or stage 4 prostate cancer							
Metastatic prostate cancer (ie, bone or other metastasis)							
□ Post radical prostatectomy with adverse laboratory, histologic, or biopsy features, as indicated by <b>1</b>							
or more of the following:							
Extracapsular extension of tumor							
Invasion of seminal vesicle							
Lymph node metastasis							
Positive biopsy margin(s)							
PSA detectable							

□ Breast cancer, with <b>1 or more</b> of the following:							
□ Adjuvant therapy needed, <sup>[Δ]</sup> and <b>ALL</b> of the follow	ng:						
□ Administered in combination with tamoxife	n or an aromatase inhibitor (eg, exemestane)						
□ Patient is premenopausal.							
□ Tumor is estrogen receptor positive or prog	gesterone receptor positive.						
□ Advanced disease, <sup></sup> and <b>ALL</b> of the following:							
Palliative treatment							
Patient is premenopausal or perimenopaus	sal.						
□ Prevention of premature ovarian failure needed, and <b>ALL</b> of the following:							
Patient is receiving cytotoxic agent associa cyclophosphamide).	ited with premature ovarian failure (eg,						
Patient is premenopausal.							
If not, please provide <b>clinical rationale</b> for formulary exce	ption:						
□ Continuation Requests: (Clinical documentation	required for all requests)						
Patient had an <u>adequate response</u> or <u>significant improvement</u> while on this medication.							
If not, please provide clinical rationale for continuing this n	nedication:						
ACKNOWLEDGEMENT							
Request By (Signature Required):	Date: / /						

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.



### Prior Authorization Group – Camcevi PA

#### Drug Name(s): CAMCEVI

#### LEUPROLIDE INJECTABLE

#### Criteria for approval of Prior Authorization Drug:

- 1. Prescribed for an approved FDA diagnosis (as listed below):
- 2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

#### **Exclusion Criteria:**

- Hypersensitivity to leuprolide, gonadotropin releasing hormone (GnRH), GnRH agonists or any of the excipients in the formulations
- Pregnancy
- Undiagnosed and abnormal uterine bleeding

# Prescriber Restrictions:

N/A

**Coverage Duration:** Initial approval will be for 6 months. Continuation may be approved for up to 12 months.

#### **FDA Indications:**

#### Camcevi

• Prostate Cancer, Advanced

#### **Off-Label Uses:**

- Breast Cancer
- Gender Dysphoria Transgender female; Adjunct
- Ovarian Cancer
- Prostate Cancer, Localized
- Prostate Cancer, Neoadjuvant treatment
- Uterine Leiomyoma
- Thyroid eye disease (Moderate to Severe), Active

#### Age Restrictions:

2 years and older

Other Clinical Considerations: N/A

Resources: https://careweb.careguidelines.com/ed28/ac/ac04\_007.htm#top