SAMPLE LETTER OF MEDICAL NECESSITY

Payers may require a letter of medical necessity to process and cover a claim for medications not currently covered by the payer, including newly FDA approved medications. This allows the payer to review the reason for the requested therapy and to determine medical appropriateness. A patient-specific letter will help to explain the healthcare professional's rationale and clinical decision making in choosing a specific therapy. Below is a sample letter that can be customized based on your patient's medical history and your rationale for the prescribed treatment. Note that some payers may have specific forms that must be completed based on their processes.

To Prescriber: Please refer to the Important Safety Information in the Full Prescribing Information, including BOXED WARNING, when determining whether BIJUVA™(estradiol and progesterone) capsules is medically appropriate for the individual patient.

DATE: [*Month, Day, Year*]

TO: [*Health Plan or Pharmacy Benefit Manager*]
[*Address*]
[*City, State, Zip Code*]

FROM: [*Heath Care Provider Name*]

SUBJECT: Letter of Medical Necessity and request for insurance coverage and reimbursement for BIJUVA™(estradiol and progesterone) capsules

To Whom It May Concern:

I am requesting insurance coverage and reimbursement for BIJUVA (estradiol and progesterone) capsules through Medical Necessity on behalf of my patient:
[*Patient Name*]
[*Policy #/Group #*]
[*Date of Birth*]
[*Diagnosis*]

This request is supported by the following information:

Summary of Patient's Diagnosis:
[*Insert patient's diagnosis, date of diagnosis, and current condition*].

Rationale for Treatment with BIJUVA

BIJUVA is approved as a treatment for moderate to severe hot flashes due to menopause in women with a uterus. BIJUVA is the only available FDA approved combination of bio-identical* estradiol and bio-identical progesterone in a single oral capsule. No other combination of bio-identical estradiol and bio-identical progesterone has been studied and approved for use by the FDA.
[*Describe the patient's treatment history, including lab test results, prior and current treatment regimens, and treatment outcomes*].
[*Insert additional clinical basis for prescribing BIJUVA which may include published medical study data and/or FDA approved prescribing information*].

In summary, BIJUVA is necessary for this patient's medical condition. I appreciate your approval of this request for insurance coverage and reimbursement for BIJUVA. If you have any further questions regarding this matter, or need additional information, please do not hesitate to contact my office at [*Phone Number*].

Sincerely,

[*Health Care Provider name], [Degree*]
[*NPI Number*]
[*Phone Number*]
[*Fax Number*]

Enclosures: [*Attach as appropriate*]

*There is no evidence that bio-identical hormones are safer or more effective than synthetic hormones

SAMPLE LETTER OF MEDICAL NECESSITY

INDICATION

BIJUVA™ is a combination of estradiol and progesterone indicated in a woman with a uterus for the treatment of moderate to severe vasomotor symptoms due to menopause.

IMPORTANT SAFETY INFORMATION

WARNING: CARDIOVASCULAR DISORDERS, BREAST CANCER, ENDOMETRIAL CANCER, AND PROBABLE DEMENTIA

See full prescribing information for complete boxed warning.

Estrogen Plus Progestin Therapy

- **Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia**
- **The Women's Health Initiative (WHI) estrogen plus progestin substudy reported increased risks of stroke, deep vein thrombosis (DVT), pulmonary embolism (PE), and myocardial infarction (MI)**
- **The WHI estrogen plus progestin substudy reported increased risks of invasive breast cancer**
- **The WHI Memory Study (WHIMS) estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age or older**

Estrogen-Alone Therapy

- **There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens**
- **Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia**
- **The WHI estrogen-alone substudy reported increased risks of stroke and DVT**
- **The WHIMS estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age or older**

CONTRAINDICATIONS

- BIJUVA is contraindicated in women with any of the following conditions: Undiagnosed abnormal genital bleeding; Known, suspected, or history of cancer of the breast; Known or suspected estrogen- dependent neoplasia; Active DVT, PE, or history of these conditions; Active arterial thromboembolic disease (for example, stroke, MI), or a history of these conditions; Known anaphylactic reaction, angioedema, or hypersensitivity to BIJUVA or any of its ingredients; Known liver impairment or disease; Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders.

WARNINGS AND PRECAUTIONS

- An increased risk of PE, DVT, stroke, and MI has been reported with estrogen plus progestin therapy. Should these occur or be suspected, therapy should be discontinued immediately. Risk factors for arterial vascular disease and/or venous thromboembolism (VTE) should be managed appropriately.
- The WHI substudy of daily estrogen plus progestin after a mean follow-up of 5.6 years reported an increased risk of invasive breast cancer. Observational studies have also reported an increased risk of breast cancer for estrogen plus progestin therapy after several years of use. The risk increased with duration of use and appeared to return to baseline over about 5 years after stopping treatment (only the observational studies have substantial data on risk after stopping). The use of estrogen plus progestin therapy has been reported to result in an increase in abnormal mammograms requiring further evaluation.
- Endometrial hyperplasia (a possible precursor to endometrial cancer) has been reported to occur at a rate of approximately less than one percent with BIJUVA™. Clinical surveillance of all women using estrogen plus progestin therapy is important. Adequate diagnostic measures should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding.
- The WHI estrogen plus progestin substudy reported a statistically non-significant increased risk of ovarian cancer. A meta-analysis of 17 prospective and 35 retrospective epidemiology studies found that women who used hormonal therapy for menopausal symptoms had an increased risk for ovarian cancer. The exact duration of hormone therapy use associated with an increased risk of ovarian cancer, however, is unknown.
- In the WHIMS ancillary studies of postmenopausal women 65 to 79 years of age, there was an increased risk of developing probable dementia in women receiving estrogen plus progestin when compared to placebo. It is unknown whether these findings apply to younger postmenopausal women.
- Estrogens increase the risk of gallbladder disease.
- Discontinue estrogen if severe hypercalcemia, loss of vision, severe hypertriglyceridemia, or cholestatic jaundice occurs.
- Monitor thyroid function in women on thyroid replacement hormone therapy.

ADVERSE REACTIONS

The most common adverse reactions (≥3%) for BIJUVA are breast tenderness (10.4%), headache (3.4%), vaginal bleeding (3.4%), vaginal discharge (3.4%) and pelvic pain (3.1%).

Please note that this information is not comprehensive. Please see the Full Prescribing Information including BOXED WARNING at www.BIJUVA.com.

BJVA-20064 1/2019