**FOR INFORMATIONAL USE ONLY**: This is a sample Letter of Medical Necessity. It is not intended to replace your diagnosis of the patient’s medical condition or recommendation for a particular treatment. If used, you may want to consider transferring to your practice’s letterhead before printing.

[Month day, year]

ATTN: [Medical Director] [Payer name]

[Payer contact name] [Payer address]

Re: Letter of Medical Necessity for BESREMi® (ropeginterferon alfa-2b-njft)

**Patient:** [Patient’s first and last name] **Subscriber ID#:** [Insurance ID #]

**Group #:** [Insurance group #]

Dear [Medical Director],

I am writing on behalf of my patient, [patient name], to document medical necessity for treatment with BESREMi. Based on my experience in managing [disease state], I believe BESREMi is medically necessary and appropriate for my patient. This letter provides information about the patient’s medical history and diagnosis, and a statement summarizing my treatment rationale. On behalf of the patient, I am requesting approval for use of, and subsequent payment for, the treatment. BESREMi is indicated for the treatment of adults with polycythemia vera.

**Patient History and Diagnosis**

[Patient name], is [a/an] [age]-year-old [male/female] who was diagnosed with [ICD- 10 code] [diagnosis name] on [month day, year]. As a result of [diagnosis], my patient [enter brief description of patient history]. Additionally, [patient name] has tried [state previous surgeries and/or therapies] and [state outcomes]. Please see enclosed documentation of my patient’s medical history, and supporting information relating to my request to treat [patient name] with BESREMi.

**Treatment Information**

BESREMi® is a subcutaneous injection indicated for the treatment of adults with polycythemia vera. Approved by the FDA in \_\_\_\_ 2021. The safety and efficacy profile of BESREMi makes it a necessary and appropriate option for [patient name]. [Include any additional clinical rationale explaining the medical necessity of this treatment.]

**Supporting Documentation**

The following items are enclosed [Note: The below items are suggested enclosures and anything not applicable can be deleted]:

* [Package Insert for BESREMi
* [ICD-10 code, diagnosis name, and dates]
* [Past treatments and/or patient’s history of failed treatments
* [Laboratory results that support appropriateness for BESREMi

Please consider coverage of BESREMi on [patient name]’s behalf and approve use and subsequent payment for BESREMi. If you have any further questions regarding this matter, please do not hesitate to call me at [physician’s phone number]. Due to the urgent nature of [diagnosis name], I’d like to thank you for your prompt attention to this matter.

Thank you very much for your time and consideration.

**IMPORTANT SAFETY INFORMATION**

**What is the most important information I should know about BESREMi?**

**BESREMi can cause serious side effects that may cause death or may worsen certain serious diseases that you may already have. Tell your healthcare provider right away if you have any serious side effects during treatment with BESREMi. If symptoms get worse, or become severe and continue, your healthcare provider may tell you to stop taking BESREMi. These symptoms may go away in some people after they stop taking BESREMi.**

* Mental health problems, including suicide: BESREMi may cause you to develop mood or behavior problems that may get worse during treatment with BESREMi or after your last dose, including irritability (getting upset easily), restlessness and agitation, confusion, depression (feeling low, feeling bad about yourself or feeling hopeless), unusually grand ideas, acting aggressive, acting impulsively, or thoughts of hurting yourself or others, or thoughts of suicide. If you develop any of these symptoms, you, your caregiver, or family member should call your healthcare provider immediately. Your healthcare provider should carefully monitor you during treatment with BESREMi.
* New or worsening autoimmune problems: BESREMi may cause autoimmune problems (a condition where the body’s immune cells attack other cells or organs in the body), including thyroid problems, increased blood sugar (hyperglycemia), and type I diabetes. In some people who already have an autoimmune problem, it may get worse during your treatment with BESREMi. Tell your healthcare provider if you have tiredness, are urinating often, or if you are very thirsty.
* Heart problems: BESREMI may cause heart problems, including problems with your heart muscle (cardiomyopathy), heart attack, abnormal heart rhythm (atrial fibrillation), and decreased blood flow to your heart. You should not use BESREMi if you have high blood pressure that is not controlled, congestive heart failure, a serious abnormal heart rhythm, narrowing of the arteries to your heart, certain types of chest pain (angina), or a recent stroke or heart attack. If you have a heart problem before you start using BESREMi, your healthcare provider should monitor you closely during treatment with BESREMi.

**Who should not use BESREMi?**

Do not use BESREMi if you:

* have or had severe mental health problems, especially severe depression, thoughts of suicide, or attempted suicide
* have or had a serious or untreated autoimmune disease
* have had a serious allergic reaction to another interferon product or to any of the ingredients in BESREMi. Symptoms of a serious allergic reaction may include itching, swelling of your face, tongue, throat, trouble breathing, feeling dizzy or faint, and chest pain
* have certain types of liver problems
* have received a transplant and take immunosuppressive medicines

**Before using BESREMi, tell your healthcare provider about all of your medical conditions, including if you:**

* are being treated for a mental illness or had treatment in the past for any mental illness, including depression and have had thoughts of hurting yourself or others
* have type 1 diabetes
* have or ever had any problems with your heart, including heart attack or high blood pressure
* have or ever had bleeding problems, a blood clot, or low blood cell counts
* have a condition that suppresses your immune system, such as certain cancers
* have hepatitis B or HIV infection
* have kidney or liver problems
* are pregnant or plan to become pregnant. BESREMi may harm your unborn baby and may cause loss of your pregnancy (miscarriage).
	+ Before you start using BESREMi your healthcare provider should do a pregnancy test.
	+ You should use effective birth control during treatment and for at least 8 weeks after your final dose of BESREMi. Talk to your healthcare provider about birth control choices for you during treatment with BESREMi.
	+ BESREMi can affect your menstrual cycles and may cause your menstrual periods to stop.
	+ Tell your healthcare provider if you become pregnant during treatment with BESREMi.
* are breastfeeding or plan to breastfeed. It is not known if BESREMi passes into your breast milk. You should not breastfeed during treatment and for 8 weeks after your final dose of BESREMi.

**What are the possible side effects of BESREMi?**

BESREMi can cause serious side effects including:

* Decreased blood cell counts: Your healthcare provider should check your blood cell counts before you start and during treatment with BESREMi. If your blood cell counts are too low you can develop anemia, infections or have problems with bleeding or bruising.

Call your healthcare provider right away if you develop weakness and tiredness, bruising easily, nose bleeds often, fever, chills, burning and painful urination, urinating often, or coughing up yellow or pink mucus (phlegm)
* Serious allergic reactions and skin reactions: Get medical help right away if you get any of the following symptoms: skin rash or hives; itching; swelling of the face, eyes, lips, tongue or throat; trouble breathing; chest pain; or feeling faint
* Eye problems: BESREMi can cause severe eye problems with your retinas that can lead to vision loss or blindness. You should have an eye exam before and during treatment with BESREMi if you have diabetes or high blood pressure and also have retinal problems. Your healthcare provider may stop BESREMi if you develop new or worse eye problems during treatment with BESREMi.
* Liver problems: BESREMi can cause increases in liver enzymes and liver damage. Your healthcare provider should do blood tests to monitor your liver enzymes and liver function before you start and during treatment with BESREMi.
* Kidney problems: Your healthcare provider will do blood tests to check your kidney function before starting and during treatment with BESREMi. Tell your healthcare provider right away if you develop any symptoms of a kidney problem, including changes in the amount or color of your urine, blood in your urine, swelling in your ankles, or loss of appetite. Your healthcare provider may stop BESREMi if you develop severe kidney problems.
* Tooth and gum (periodontal) problems: BESREMi can cause tooth and gum problems which can lead to tooth loss. BESREMi can also cause problems with dry mouth that can damage your teeth and the lining of the mouth during long-term treatment with BESREMi. It is important for you to brush your teeth well, two times each day and have regular dental examinations during treatment with BESREMI.
* Skin problems: BESREMi can cause skin problems. Signs and symptoms of a skin problem with BESREMi include itching, hair loss, rash, redness, psoriasis, acne, thickening of the skin, or excessive sweating. Call your healthcare provider if you develop a rash that is bothersome or covers a large skin area.

The most common side effects of BESREMi include:

* flu like symptoms including tiredness, weakness, fever, chills, muscle aches, and joint pain
* itching
* sore throat

Please see full [Prescribing Information](https://us.pharmaessentia.com/wp-content/uploads/2021/11/BESREMi-USPI-November-2021-1.pdf), including Boxed Warning, and [Medication Guide](https://us.pharmaessentia.com/wp-content/uploads/2021/11/BESREMi-USPI-November-2021-1.pdf#page=18) for BESREMi.

 **What is BESREMi?**

BESREMi is a prescription medicine that is used to treat adults with polycythemia vera

Sincerely,

[Physician’s signature]

[Physician’s name and credentials]

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