

[Physician Letterhead]

[Select Today's Date]

[Name of Health Insurance Company]

[PO Box or Street Address]

[City], [State] [Zip Code]

Re: [Patient Name]

Policy Number: [Policy Number]

Group Number: [Group Number]

To whom it may concern:

[Patient Name] is a [age]-year-old female under my care for [disease]. She was first diagnosed with [state diagnosis] on [Select Diagnosis Date]. This letter provides information about the patient's medical history and diagnosis, and a request for approval and subsequent payment for treatment using Zejula (niraparib).

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]. The attached medical records document [Patient Name]'s clinical condition and medical necessity for treatment with ZEJULA.

The FDA approved ZEJULA in March 2017. ZEJULA is a poly(ADP-ribose) polymerase (PARP) inhibitor and it is indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. In October 2019, the FDA approved an additional indication for Zejula for the treatment of advanced ovarian, fallopian tube, or primary peritoneal cancer patients, who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:

- A deleterious or suspected deleterious BRCA mutation, or
- genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy.

Patient selection is based on an FDA-approved companion diagnostic for Zejula.

This letter serves to document that [Patient Name] has a diagnosis of [diagnosis] and needs treatment with ZEJULA, and that ZEJULA is medically necessary for her as prescribed.

At this time, the treatment plan is to immediately start the patient on ZEJULA, and to treat until disease progression or unacceptable toxicity. [Patient Name] will be treated according to label at [state dosing regimen]. The treatment goal is [state treatment objectives]. In my professional opinion, ZEJULA is medically necessary and an appropriate drug for my patient at this time.

If you have any further questions regarding this matter, please do not hesitate to call me at [physician telephone number]. Given the urgent nature of this request, thank you for your prompt attention to this matter.

Sincerely,

[Physician Name, Credentials]

[Physician Signature]

[Provider Identification Number]

Enclosures:

Copies of patient medical records

[List enclosures]

ZEJULA package insert

ZEJADR1000