

Dear Health Care Provider:

We have provided this **sample Letter of Medical Necessity** to help support you in navigating the coverage process. This sample letter may be utilized to help justify your patient's need for treatment with ORSERDU® (elacestrant).

To use this letter, please feel free to copy or modify the text from the next page and paste it onto your practice letterhead. Be sure to provide all bolded and bracketed text with the appropriate patient-specific information before forwarding your customized letter to your patient's insurance provider.

Tips for completing the disease and medical history fields:

- Include specific ICD-10-CM codes
- List previous therapy, length of therapy, and outcomes (specify reasons for unsuccessful results)
- Clearly state the rationale for the recommended therapy and why it is appropriate for your patient

Tips for completing the Enclosures field:

- List and attach documents that support your rationale for the recommended therapy:
 - o Summary of patient's medical records
 - o Clinical Studies/Journal articles
 - o Specific information about ORSERDU® such as prescribing information, FDA approval letter, treatment guidelines from professional practice organizations.

Disclaimer: This is presented for informational purposes only and is not intended to provide reimbursement or legal advice. For your independent consideration and review, please make all changes that you deem appropriate. The treating practitioner in his or her medical judgment is ultimately responsible for the accuracy, truthfulness, and completeness of all claims and communications submitted to third-party payers. Nothing in this document should be construed as a guarantee by Stemline Therapeutics, Inc. regarding coverage or payment by any payor at any specific level, and Stemline Therapeutics, Inc. does not advocate or promote the appropriateness of the use of any billing codes. This template is intended for determining medical necessity and meeting general prior authorization requirements. Please see the ORSERDU® FDA-approved label for information relevant to any prescribing decisions.

[Practice Letterhead]

Date: [Insert Date]
[Pharmacy Director/Medical Director]
[Insurance Company]
[Address]
[City, State, ZIP code]

RE: [Patient Name]
[Patient Date of Birth]
[Patient Insurance Number]
[Group Number]

REQUEST: Authorization for treatment with ORSERDU® (elacestrant)
DIAGNOSIS: [ICD-10-CM Code(s)]
DOSE and FREQUENCY: 345 mg, QD, with food
REQUEST TYPE: __ Expedited __ Standard

Dear [insert name],

I am writing on behalf of my patient, [insert patient name], to document the medical necessity for ORSERDU® (elacestrant) for [indication]. This request is supported by the following information:

Patient Diagnosis, Condition, & History:

- [Patient's diagnosis, date of diagnosis]
- [Lab results and date* ESR1 Test results if prior therapy had unsuccessful results]
- [Patient's current medical condition]
- [Patient's previous treatments, dose, duration, reason(s) for discontinuation]

Rationale for Treatment

Considering the patient's history, current medical condition, and the supporting uses of ORSERDU®, the only FDA approved therapy indicated for ER positive HER2 negative ESR1 mutated mBC with disease progression following at least one line of endocrine therapy.

Given the urgent nature of this request, please provide a timely authorization. Please contact my office at [insert phone number] if you require additional information.

Sincerely,

[Physician's name & signature]
[Physician's NPI]

Enclosures: [List and enclosures; examples may include medical records, prescribing information, clinical trial information, medication guide]