Sample Letter of Medical Necessity for WILSERDLY™ (giredestrant)

Instructions for Use

When submitting a prior authorization (PA), medical exception or coverage determination request to a patient's health insurance plan, including a letter of medical necessity may help explain the rationale and clinical decision-making behind the choice to prescribe WILSERDLY.

Please note that using the information in this sample letter does not guarantee that the health plan will provide reimbursement for WILSERDLY. It is not intended to be a substitute for, or influence on, the independent medical judgment of the physician. This letter is provided for informational purposes and does not constitute medical, legal or reimbursement advice. Reimbursement laws, regulations and third-party payer policies are subject to change. Please verify specific coverage, prior authorization and reimbursement requirements directly with the applicable payer.

Some Key Reminders:

- Include the appropriate ICD-10-CM diagnosis code(s)
    - For a list of sample coding, visit **Genentech-Pro.com/WILSERDLY**
- Please ensure the treating physician signs the letter
- Please refer to page 3 for the list of enclosures and the appendix for commonly requested patient information for a WILSERDLY medical necessity review

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[Date]

[Payer name]
ATTN: [Contact Title/Medical Director]
[Payer Address]
[City, State ZIP]

Subject: **Letter of Medical Necessity for WILSERDLY™ (giredestrant)**

Patient: [Patient name]
Date of Birth: [MM/DD/YYYY]
Subscriber ID #: [Insurance ID #]
Subscriber Group #: [Insurance group #]
Case ID Number: [Case ID Number (if available)]
Dates of Service: [Include all dates of service]

Dear [Contact Name/Medical Director],

I am writing on behalf of my patient, [first and last name], to [request prior authorization of/document medical necessity] [for] treatment with WILSERDLY. This letter provides information about the patient's medical history and diagnosis and a summary of the treatment plan.

On November 16, 2026, the FDA approved WILSERDLY as an estrogen receptor (ER) antagonist indicated:

- [For the adjuvant treatment of adults with ER-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-), stage I, II and III breast cancer at intermediate to high risk of recurrence]
- [In combination with everolimus for the treatment of adults with ER+, HER2-, *ESR1*-mutated locally advanced or metastatic breast cancer, as detected by an FDA-authorized test, whose disease has recurred during or after completion of endocrine-based adjuvant therapy, or has progressed on at least one endocrine-based regimen in the metastatic setting]

Patient's Clinical History
[Patient's name] is [a/an] [age]-year-old [male/female/transgender/etc.] who as of [date], has been diagnosed with:

- [ER+, HER2-, stage [I/II/III] breast cancer at intermediate to high risk of recurrence]
- [ER+, HER2-, *ESR1*-mutated locally advanced or metastatic breast cancer, whose disease has recurred during or after completion of endocrine-based adjuvant therapy, or has progressed on at least one endocrine-based regimen in the metastatic setting]

This patient has been under my care since [date], having been referred to me by [referring physician's name] for [reason].

[Brief summary of rationale for treatment with WILSERDLY. This may include a brief description of the patient's diagnosis, including the ICD-10-CM code, the severity of the patient's condition, prior treatment(s), the duration of each treatment, responses to those treatments, the

rationale for discontinuation, as well as other factors (e.g., underlying health issues, age) that have affected your treatment selection. See the enclosures and appendix at the end for a list of commonly requested clinical documentation/information for WILSERDLY medical necessity reviews.]

Treatment Plan
[Include plan of treatment (dosage, length of treatment) and clinical practice guidelines that support the use of WILSERDLY. Consider mentioning experts in the field who also support the treatment.]

Summary
Based on the above facts, I believe WILSERDLY is not only indicated, but also medically necessary for this patient. If you have any further questions, please contact me at [phone number] or [email address]. Thank you for your time and consideration.

Sincerely,
[Physician's name, credentials and signature]

Enclosures [List enclosures, which may include:

- Drug documentation:
  - WILSERDLY Prescribing Information
  - FDA approval letter for WILSERDLY
  - Relevant peer-reviewed articles
- Patient medical records:
  - Clinical notes/medication list
  - Imaging reports
  - Pathology reports
  - Laboratory or molecular testing results]

Appendix
Commonly requested patient information for a WILSERDLY medical necessity review may include:

- **For patients with <u>early breast cancer</u>,** patient records with the following clinical information:
  - Age
  - Menopausal status
  - Diagnosis, including:
    - Stage of disease (e.g., I-III)
    - Biomarker testing results (e.g., ER+, HER2-)
    - Clinical and pathological features defining the risk of recurrence (e.g., nodal status, tumor size, histological grade, Ki67 index, genomic test score)
  - Prior treatments (e.g., surgery, adjuvant breast cancer medications if applicable)
  - Planned giredestrant dosing and frequency (e.g., 30 mg taken orally once daily for 5 years or until disease recurrence or unacceptable toxicity)

- **For patients with <u>locally advanced or metastatic breast cancer</u>,** patient records with the following clinical information:
    - Age
    - Menopausal status
    - Diagnosis, including:
        - Stage of disease (e.g., III-IV)
        - Biomarker testing results (e.g., ER+, HER2-)
        - Gene mutation testing results (e.g., *ESR1* mutant)
    - Prior treatments (e.g., adjuvant and first-line metastatic breast cancer medications, including endocrine therapies and CDK4/6 inhibitors, etc.)
    - Evidence of recurrence or disease progression
    - Planned concomitant medications (e.g., everolimus)
    - Planned giredestrant dosing and frequency (e.g., 30 mg taken orally once daily until disease progression or unacceptable toxicity)