Sample Letter of Appeal for WILSERDLY™ (giredestrant)

Instructions for Use
This letter provides an example of the types of information that may be provided when a patient's insurance company denies coverage or prior authorization (PA) for 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
- You may use an appeal letter for a claim (when reimbursement for a claim is underpaid or denied) or when a PA, medical exception or coverage determination is denied
- Please indicate the type and the level of appeal for which you are filing
- 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 4 for the list of enclosures

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[Date]

[Payer name]
ATTN: APPEALS
[Payer Address]
[City, State ZIP]

Subject: **Letter of Appeal for WILSERDLY™ (giredestrant)**

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

Dear Appeals Reviewer,

I am writing to request [a/an] [indicate level of appeal: 1st, 2nd, etc.] [appeal/redetermination/reconsideration] of the denial of coverage for WILSERDLY, which I have prescribed for my patient, [Patient First and Last Name].

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]

As noted in the denial letter, coverage for WILSERDLY was not approved due to [list reason(s) for the denial]. I understand from your letter that the [claim/reimbursement/prior authorization] was [denied/underpaid] based on [denial reason(s)]. I would like to address [the reason/those reasons] now. I would appreciate prompt review of the enclosed information demonstrating medical necessity and coverage of WILSERDLY.

OR

I am writing to request [a/an] [indicate level of appeal: 1st, 2nd, etc.] [appeal/redetermination/reconsideration] of WILSERDLY on behalf of my patient, [Patient's first and last name]. I acknowledge your health plan's policy and I understand from your letter that the denials were based on [denial reason(s)]. I would like to address [the reason/those reasons] now. I would appreciate prompt review of the enclosed information demonstrating medical necessity and coverage of WILSERDLY. Listed below are the patient's medical history, diagnosis and treatment plan, which confirm the medical necessity and appropriate

treatment with WILSERDLY.

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]

Include:

- [Diagnosis and dates]
- [ICD-10-CM diagnosis codes]
- [Any past treatments]
- [Any test results that indicate failure of past treatment(s)]
- [Extenuating circumstances that would preclude alternatives to WILSERDLY]
- [Social and family information]
- [REMINDER: If a payer has a published policy, include here.]
- [REMINDER: If state statute exists, include here.]

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 therapy, the duration and response to that treatment, the rationale for discontinuation, as well as other factors that have affected your treatment selection. See the enclosures and appendix on the next page 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. I am requesting that you reconsider coverage based on the information above. I am readily available at my office phone [Physician phone number] or via email at [Physician email] to address any questions or concerns you might have regarding this appeal. Thank you for your time and consideration.

Sincerely,

[Physician signature]

[Physician typed name and credentials]

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 includes:

- **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* mutation)
  - 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)