



## Preparing a Coverage Authorization Appeals Letter

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage policies. For more information, please call Verzenio Continuous Care™ at 1-844-VERZENIO.

**If the patient's initial claim or Coverage Authorization Request Letter is denied by the patient's health plan, the payer may require a Coverage Authorization Appeals Letter. Depending on the plan, there may be varying levels of appeals. If you are uncertain about a plan's appeal levels or specific procedures, always refer to the plan's appeal guidelines.**

This resource, **Preparing a Coverage Authorization Appeals Letter**, provides information to healthcare providers (HCPs) when appealing a coverage authorization decision for a patient's plan. Included on the following page is a list of considerations, which can be followed when creating a Coverage Authorization Appeals Letter. In addition, two sample letters are attached to this document and feature information that many plans require to process a coverage authorization appeal. Follow the patient's plan requirements when requesting Verzenio, otherwise treatment may be delayed.

**A Coverage Authorization Appeals Letter** originates from the patient and the prescribing HCP.\* It should be submitted with two additional items: the patient's medical records and a Letter of Medical Necessity. Also see **Composing a Letter of Medical Necessity (LMN)** for more information.

\* For Medicare beneficiaries, specific requirements must be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please visit <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/downloads/partdmanualchapter18.pdf>.

### Indication

Verzenio is indicated for the treatment of hormone receptor–positive (HR+), human epidermal growth factor receptor 2–negative (HER2–) advanced or metastatic breast cancer (MBC):

- In combination with fulvestrant for women with disease progression following endocrine therapy
- In combination with an aromatase inhibitor (AI) for postmenopausal women as initial endocrine-based therapy
- As a single agent for adult patients with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

### Select Important Safety Information

**Diarrhea** occurred in 81% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 86% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and 90% of patients receiving Verzenio alone in MONARCH 1. Grade 3 diarrhea occurred in 9% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 13% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and in 20% of patients receiving Verzenio alone in MONARCH 1. Episodes of diarrhea have been associated with dehydration and infection.

Diarrhea incidence was greatest during the first month of Verzenio dosing. In MONARCH 3, the median time to onset of the first diarrhea event was 8 days, and the median duration of diarrhea for Grades 2 and 3 were 11 and 8 days, respectively. In MONARCH 2, the median time to onset of the first diarrhea event was 6 days, and the median duration of diarrhea for Grades 2 and 3 were 9 days and 6 days, respectively. In MONARCH 3, 19% of patients with diarrhea required a dose omission and 13% required a dose reduction. In MONARCH 2, 22% of patients with diarrhea required a dose omission and 22% required a dose reduction. The time to onset and resolution for diarrhea were similar across MONARCH 3, MONARCH 2, and MONARCH 1.

Instruct patients that at the first sign of loose stools, they should start antidiarrheal therapy such as loperamide, increase oral fluids, and notify their healthcare provider for further instructions and appropriate follow-up. For Grade 3 or 4 diarrhea, or diarrhea that requires hospitalization, discontinue Verzenio until toxicity resolves to ≤Grade 1, and then resume Verzenio at the next lower dose.

Please see Important Safety Information on pages 5 and 6 and click to access the full [Prescribing Information](#) for Verzenio.





## Preparing a Coverage Authorization Appeals Letter

### Coverage Authorization Requests: Guidance and Recommendations

1. Include the patient's full name, plan identification number, and date of birth.
2. Add the prescribing HCP's National Provider Identifier (NPI) number and specialty.
3. Disclose that you are familiar with the plan's policy. Clearly document the basis for the plan's denial within the letter, along with case identification number from the initial denial letter.
4. Provide a copy of the patient's records with the following details:
  - Patient must have a diagnosis of HR+, HER2– advanced or metastatic breast cancer\*
  - Patient must also have one of the following:
    - For Verzenio in combination with an aromatase inhibitor, no prior systemic therapy in the advanced or metastatic setting
    - For Verzenio in combination with fulvestrant, disease progression following endocrine therapy
    - For Verzenio taken as a single agent, disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
5. Document prior treatments and the duration of each; describe the rationale for discontinuation.
6. Explain why the plan's preferred formulary agents are not appropriate for the patient.
7. Provide the clinical rationale for treatment; this information may be found in the Verzenio prescribing information and/or clinical peer-reviewed literature.
8. Summarize your recommendation at the end of the letter.
9. Include an LMN.

\*Hormone receptor–positive (HR+) and human epidermal growth factor receptor 2–negative (HER2–).



# Sample Coverage Authorization Appeals Letter

HCPs can follow this format for patients who are **NOT** currently receiving treatment with Verzenio™ (abemaciclib).

[Date]  
 [Prior Authorization Department] Re: [Patient's Name]  
 [Name of Health Plan] [Plan Identification Number]  
 [Mailing Address] [Date of Birth]

To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of medications within this class. We are requesting that you reassess your recent denial of Verzenio™ (abemaciclib) coverage. We understand that the reason for your denial is [copy reason verbatim from the plan's denial letter]. However, we believe that Verzenio [dose, frequency] is the appropriate treatment for the patient. In support of our recommendation for Verzenio treatment, we have provided an overview of the patient's relevant clinical history below.

**Patient's history, diagnosis, condition, and symptoms\*:**  
 Patient must have a diagnosis of HR+, HER2– advanced or metastatic breast cancer†

**Patient must also have one of the following:**

- For Verzenio in combination with an aromatase inhibitor, no prior systemic therapy in the advanced or metastatic setting
- For Verzenio in combination with fulvestrant, disease progression following endocrine therapy
- For Verzenio taken as a single agent, disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

Past Treatments‡	Start/Stop Dates	Reason(s) for Discontinuing

[Provide clinical rationale for this treatment; this information may be found in the Verzenio prescribing information and/or clinical peer-reviewed literature.]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis or disease progression without treatment with Verzenio.]

Please feel free to contact me, [HCP's name], at [office phone number] or [patient's name] at [patient's phone number] for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

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[Physician's name and signature] [Patient's name and signature]  
 [Physician's medical specialty]  
 [Physician's NPI]  
 [Physician's practice name] Encl: Medical records  
 [Phone #] Clinical trial information  
 [Fax #] Letter of Medical Necessity (LMN)

[Please detail all that apply and add additional lines as needed.]

When appealing a plan's step edit therapy requirement, consider providing statements indicating why these requirements are inappropriate for the patient, including examples of previous therapy trials/failures due to lack of response or drug intolerance.

\* Include patient's medical records and supporting documentation.  
 † Hormone receptor–positive (HR+) and human epidermal growth factor receptor 2–negative (HER2–).  
 ‡ Identify drug name, strength, dosage form, and therapeutic outcome.

Please see Important Safety Information on pages 5 and 6 and click to access the full [Prescribing Information](#) for Verzenio.





# Sample Coverage Authorization Appeals Letter

HCPs can follow this format for patients who **HAVE** been treated with Verzenio™ (abemaciclib) and have had treatment interruptions.

[Date]  
 [Prior Authorization Department] Re: [Patient's Name]  
 [Name of Health Plan] [Plan Identification Number]  
 [Mailing Address] [Date of Birth]

To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of medications within this class. We are requesting that you reassess your recent denial of Verzenio™ (abemaciclib) coverage. We understand that the reason for your denial is [copy reason verbatim from the plan's denial letter]. However, we believe that Verzenio [dose, frequency] is the appropriate treatment for the patient. In support of our recommendation for Verzenio treatment, we have provided an overview of the patient's relevant clinical history below.

[In this section, describe the clinical presentation of the disease at the time when the patient was first prescribed Verzenio. In addition, include summary of patient response and improvements (if any). It may be necessary to review past medical records to gather this information.]

**Patient's history, diagnosis, condition, and symptoms\*:**  
 Patient must have a diagnosis of HR+, HER2– advanced or metastatic breast cancer†

**Patient must also have one of the following:**

- For Verzenio in combination with an aromatase inhibitor, no prior systemic therapy in the advanced or metastatic setting
- For Verzenio in combination with fulvestrant, disease progression following endocrine therapy
- For Verzenio taken as a single agent, disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

Past Treatments‡	Start/Stop Dates	Reason(s) for Discontinuing

[Provide clinical rationale for this treatment; this information may be found in the Verzenio prescribing information and/or clinical peer-reviewed literature.]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis or disease progression without treatment with Verzenio.]

Please feel free to contact me, [HCP's name], at [office phone number] or [patient's name] at [patient's phone number] for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

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[Physician's name and signature] [Patient's name and signature]  
 [Physician's medical specialty]  
 [Physician's NPI]  
 [Physician's practice name] Encl: Medical records  
 [Phone #] Clinical trial information  
 [Fax #] Letter of Medical Necessity (LMN)

[Please detail all that apply and add additional lines as needed.]

When appealing a plan's step edit therapy requirement, consider providing statements indicating why these requirements are inappropriate for the patient, including examples of previous therapy trials/failures due to lack of response or drug intolerance.

\* Include patient's medical records and supporting documentation.  
 † Hormone receptor–positive (HR+) and human epidermal growth factor receptor 2–negative (HER2–).  
 ‡ Identify drug name, strength, dosage form, and therapeutic outcome.

Please see Important Safety Information on pages 5 and 6 and click to access the full [Prescribing Information](#) for Verzenio.



## Important Safety Information

**Diarrhea** occurred in 81% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 86% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and 90% of patients receiving Verzenio alone in MONARCH 1. Grade 3 diarrhea occurred in 9% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 13% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and in 20% of patients receiving Verzenio alone in MONARCH 1. Episodes of diarrhea have been associated with dehydration and infection.

Diarrhea incidence was greatest during the first month of Verzenio dosing. In MONARCH 3, the median time to onset of the first diarrhea event was 8 days, and the median duration of diarrhea for Grades 2 and 3 were 11 and 8 days, respectively. In MONARCH 2, the median time to onset of the first diarrhea event was 6 days, and the median duration of diarrhea for Grades 2 and 3 were 9 days and 6 days, respectively. In MONARCH 3, 19% of patients with diarrhea required a dose omission and 13% required a dose reduction. In MONARCH 2, 22% of patients with diarrhea required a dose omission and 22% required a dose reduction. The time to onset and resolution for diarrhea were similar across MONARCH 3, MONARCH 2, and MONARCH 1.

Instruct patients that at the first sign of loose stools, they should start antidiarrheal therapy such as loperamide, increase oral fluids, and notify their healthcare provider for further instructions and appropriate follow-up. For Grade 3 or 4 diarrhea, or diarrhea that requires hospitalization, discontinue Verzenio until toxicity resolves to  $\leq$ Grade 1, and then resume Verzenio at the next lower dose.

**Neutropenia** occurred in 41% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 46% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and 37% of patients receiving Verzenio alone in MONARCH 1. A Grade  $\geq$ 3 decrease in neutrophil count (based on laboratory findings) occurred in 22% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 32% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and in 27% of patients receiving Verzenio alone in MONARCH 1. In MONARCH 3, the median time to first episode of Grade  $\geq$ 3 neutropenia was 33 days, and in MONARCH 2 and MONARCH 1, was 29 days. In MONARCH 3, median duration of Grade  $\geq$ 3 neutropenia was 11 days, and for MONARCH 2 and MONARCH 1 was 15 days.

Monitor complete blood counts prior to the start of Verzenio therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Dose interruption, dose reduction, or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia.

Febrile neutropenia has been reported in  $<1\%$  of patients exposed to Verzenio in the MONARCH studies. Two deaths due to neutropenic sepsis were observed in MONARCH 2. Inform patients to promptly report any episodes of fever to their healthcare provider.

Grade  $\geq$ 3 increases in **alanine aminotransferase (ALT)** (6% versus 2%) and **aspartate aminotransferase (AST)** (3% versus 1%) were reported in the Verzenio and placebo arms, respectively, in MONARCH 3. Grade  $\geq$ 3 increases in ALT (4% versus 2%) and AST (2% versus 3%) were reported in the Verzenio and placebo arms respectively, in MONARCH 2.

In MONARCH 3, for patients receiving Verzenio plus an aromatase inhibitor with Grade  $\geq$ 3 increases in ALT or AST, median time to onset was 61 and 71 days, respectively, and median time to resolution to Grade  $<3$  was 14 and 15 days, respectively. In MONARCH 2, for patients receiving Verzenio plus fulvestrant with Grade  $\geq$ 3 increases in ALT or AST, median time to onset was 57 and 185 days, respectively, and median time to resolution to Grade  $<3$  was 14 and 13 days, respectively.

For assessment of potential **hepatotoxicity**, monitor liver function tests (LFTs) prior to the start of Verzenio therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Dose interruption, dose reduction, dose discontinuation, or delay in starting treatment cycles is recommended for patients who develop persistent or recurrent Grade 2, or Grade 3 or 4, hepatic transaminase elevation.

**Venous thromboembolic events** were reported in 5% of patients treated with Verzenio plus an aromatase inhibitor as compared to 0.6% of patients treated with an aromatase inhibitor plus placebo in MONARCH 3. Venous thromboembolic events were reported in 5% of patients treated with Verzenio plus fulvestrant in MONARCH 2 as compared to 0.9% of patients treated with fulvestrant plus placebo. Venous thromboembolic events included deep vein thrombosis, pulmonary embolism, pelvic venous thrombosis, cerebral venous sinus thrombosis, subclavian and axillary vein thrombosis, and inferior vena cava thrombosis. Across the clinical development program, deaths due to venous thromboembolism have been reported. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism and treat as medically appropriate.

Verzenio can cause **fetal harm** when administered to a pregnant woman based on findings from animal studies and the mechanism of action. In animal reproduction studies, administration of abemaciclib to pregnant rats during the period of organogenesis caused teratogenicity and decreased fetal weight at maternal exposures that were similar to the human clinical exposure based on area under the curve (AUC) at the maximum recommended human dose. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with Verzenio and for at least 3 weeks after the last dose. There are no data on the presence of Verzenio in human milk or its effects on the breastfed child or on milk production. Advise lactating women not to breastfeed during Verzenio treatment and for at least 3 weeks after the last dose because of the potential for serious adverse reactions in breastfed infants. Based on findings in animals, Verzenio may impair fertility in males of reproductive potential.

Please see additional Important Safety Information on page 6 and click to access the full [Prescribing Information for Verzenio](#).

 **everyday**  
**Verzenio**<sup>™</sup>  
abemaciclib  
50 | 100 | 150 | 200 mg tablets  
twice a day

## Important Safety Information (cont'd)

The most common adverse reactions (all grades,  $\geq 10\%$ ) observed in **MONARCH 3** for **Verzenio plus anastrozole or letrozole** and  $\geq 2\%$  higher than placebo plus anastrozole or letrozole were diarrhea (81% vs 30%), neutropenia (41% vs 2%), fatigue (40% vs 32%), infections (39% vs 29%), nausea (39% vs 20%), abdominal pain (29% vs 12%), vomiting (28% vs 12%), anemia (28% vs 5%), alopecia (27% vs 11%), decreased appetite (24% vs 9%), leukopenia (21% vs 2%), creatinine increased (19% vs 4%), constipation (16% vs 12%), ALT increased (16% vs 7%), AST increased (15% vs 7%), rash (14% vs 5%), pruritus (13% vs 9%), cough (13% vs 9%), dyspnea (12% vs 6%), dizziness (11% vs 9%), weight decreased (10% vs 3%), influenza-like illness (10% vs 8%), and thrombocytopenia (10% vs 2%).

The most common adverse reactions (all grades,  $\geq 10\%$ ) observed in **MONARCH 2** for **Verzenio plus fulvestrant** and  $\geq 2\%$  higher than placebo plus fulvestrant vs placebo plus fulvestrant were diarrhea (86% vs 25%), neutropenia (46% vs 4%), fatigue (46% vs 32%), nausea (45% vs 23%), infections (43% vs 25%), abdominal pain (35% vs 16%), anemia (29% vs 4%), leukopenia (28% vs 2%), decreased appetite (27% vs 12%), vomiting (26% vs 10%), headache (20% vs 15%), dysgeusia (18% vs 3%), thrombocytopenia (16% vs 3%), alopecia (16% vs 2%), stomatitis (15% vs 10%), ALT increased (13% vs 5%), pruritus (13% vs 6%), cough (13% vs 11%), dizziness (12% vs 6%), AST increased (12% vs 7%), peripheral edema (12% vs 7%), creatinine increased (12% vs  $<1\%$ ), rash (11% vs 4%), pyrexia (11% vs 6%), and weight decreased (10% vs 2%).

The most common adverse reactions (all grades,  $\geq 10\%$ ) observed in **MONARCH 1** with Verzenio were diarrhea (90%), fatigue (65%), nausea (64%), decreased appetite (45%), abdominal pain (39%), neutropenia (37%), vomiting (35%), infections (31%), anemia (25%), thrombocytopenia (20%), headache (20%), cough (19%), leukopenia (17%), constipation (17%), arthralgia (15%), dry mouth (14%), weight decreased (14%), stomatitis (14%), creatinine increased (13%), alopecia (12%), dysgeusia (12%), pyrexia (11%), dizziness (11%), and dehydration (10%).

The most frequently reported  $\geq 5\%$  Grade 3 or 4 adverse reactions that occurred in the Verzenio arm vs the placebo arm of **MONARCH 3** were neutropenia (22% vs 2%), diarrhea (9% vs 1%), leukopenia (8% vs  $<1\%$ ), ALT increased (7% vs 2%), and anemia (6% vs 1%).

The most frequently reported  $\geq 5\%$  Grade 3 or 4 adverse reactions that occurred in the Verzenio arm vs the placebo arm of **MONARCH 2** were neutropenia (27% vs 2%), diarrhea (13% vs  $<1\%$ ), leukopenia (9% vs 0%), anemia (7% vs 1%), and infections (6% vs 3%).

The most frequently reported  $\geq 5\%$  Grade 3 or 4 adverse reactions from **MONARCH 1** with Verzenio were neutropenia (24%), diarrhea (20%), fatigue (13%), infections (7%), leukopenia (6%), anemia (5%), and nausea (5%).

Lab abnormalities (all grades; Grade 3 or 4) for **MONARCH 3** in  $\geq 10\%$  for **Verzenio plus anastrozole or letrozole** and  $\geq 2\%$  higher than placebo plus anastrozole or letrozole vs placebo plus

**anastrozole or letrozole** were increased serum creatinine (98% vs 84%; 2% vs 0%), decreased white blood cells (82% vs 27%; 13% vs  $<1\%$ ), anemia (82% vs 28%; 2% vs 0%), decreased neutrophil count (80% vs 21%; 22% vs 3%), decreased lymphocyte count (53% vs 26%; 8% vs 2%), decreased platelet count (36% vs 12%; 2% vs  $<1\%$ ), increased ALT (48% vs 25%; 7% vs 2%), and increased AST (37% vs 23%; 4% vs  $<1\%$ ).

Lab abnormalities (all grades; Grade 3 or 4) for **MONARCH 2** in  $\geq 10\%$  for **Verzenio plus fulvestrant** and  $\geq 2\%$  higher than placebo plus fulvestrant vs placebo plus fulvestrant were increased serum creatinine (98% vs 74%; 1% vs 0%), decreased white blood cells (90% vs 33%; 23% vs 1%), decreased neutrophil count (87% vs 30%; 33% vs 4%), anemia (84% vs 33%; 3% vs  $<1\%$ ), decreased lymphocyte count (63% vs 32%; 12% vs 2%), decreased platelet count (53% vs 15%; 2% vs 0%), increased ALT (41% vs 32%; 5% vs 1%), and increased AST (37% vs 25%; 4% vs 4%).

Lab abnormalities (all grades; Grade 3 or 4) for **MONARCH 1** with Verzenio were increased serum creatinine (98%;  $<1\%$ ), decreased white blood cells (91%; 28%), decreased neutrophil count (88%; 27%), anemia (68%; 0%), decreased lymphocyte count (42%; 14%), decreased platelet count (41%; 2%), increased ALT (31%; 3%), and increased AST (30%; 4%).

**Strong CYP3A inhibitors** increased the exposure of abemaciclib plus its active metabolites to a clinically meaningful extent and may lead to increased toxicity. Avoid concomitant use of ketoconazole. Ketoconazole is predicted to increase the AUC of abemaciclib by up to 16-fold. In patients with recommended starting doses of 200 mg twice daily or 150 mg twice daily, reduce the Verzenio dose to 100 mg twice daily with concomitant use of other strong CYP3A inhibitors. In patients who have had a dose reduction to 100 mg twice daily due to adverse reactions, further reduce the Verzenio dose to 50 mg twice daily with concomitant use of other strong CYP3A inhibitors. If a patient taking Verzenio discontinues a strong CYP3A inhibitor, increase the Verzenio dose (after 3 to 5 half-lives of the inhibitor) to the dose that was used before starting the strong inhibitor. Patients should avoid grapefruit products.

**Avoid concomitant use of strong CYP3A inducers and consider alternative agents.** Coadministration of Verzenio with rifampin, a strong CYP3A inducer, decreased the plasma concentrations of abemaciclib plus its active metabolites and may lead to reduced activity.

**With severe hepatic impairment** (Child-Pugh Class C), reduce the Verzenio dosing frequency to once daily. The pharmacokinetics of Verzenio in patients with **severe renal impairment** (CLcr  $<30$  mL/min), end stage renal disease, or in patients on dialysis is **unknown**. No dosage adjustments are necessary in patients with mild or moderate hepatic (Child-Pugh A or B) and/or renal impairment (CLcr  $\geq 30$ -89 mL/min).

Please see full [Prescribing Information](#) for Verzenio.

AL HCP ISI 26FEB2018

 everyday  
**Verzenio**<sup>™</sup>  
abemaciclib  
50 | 100 | 150 | 200 mg tablets  
twice a day

