



August 9, 2023

Tim Noel
Chief Executive Office, UnitedHealthcare
Medicare & Retirement
UnitedHealth Group

Dr. Lucy Langer
National Medical Director of Oncology &
Genomics
UnitedHealth Group

Via Electronic Communication

Re: Step Therapy Damages the Health of Patients with Breast Cancer

Dear Mr. Noel and Dr. Langer:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are reaching out to express our concerns with UnitedHealthcare's decision to limit access to CDK4/6 inhibitors for patients with breast cancer. Step therapy policies that require patients to try and fail on multiple medications before being able to access the originally prescribed treatment force patients to endure symptoms without relief, leading to disease progression, and, in some cases, death.

Therefore, we urge UnitedHealthcare to **revise and remove its double step-therapy policy for CDK4/6 treatments** and ensure patients with breast cancer have equal access to all CDK4/6 treatments.

I. Background

Approximately 240,000 individuals are diagnosed with breast cancer each year.¹ Breast cancer is a type of cancer that occurs in either one or both breasts.² While breast cancer can occur in biological males, this cancer primarily impacts biological women.³ Recent studies have found that breast cancer is most fatal in Black women compared to all other women.⁴

In determining the most appropriate treatment for a patient with breast cancer, health care providers must determine if the cancer is HER2 positive or negative, as well as, if the cancer is hormone receptor positive or negative. HER2 is a protein found within breast cancer cells that causes the cancer to grow and spread faster than cancers that do not have the HER2 protein.⁵

¹ Centers for Disease Control, *Basic Information About Breast Cancer*, https://www.cdc.gov/cancer/breast/basic_info/index.htm#:~:text=Each%20year%20in%20the%20United,cancer%20than%20all%20other%20women.

² American Cancer Society, *What is Breast Cancer*, <https://www.cancer.org/cancer/types/breast-cancer/about/what-is-breast-cancer.html>.

³ *Id.*

⁴ Centers for Disease Control, *Basic Information About Breast Cancer*, https://www.cdc.gov/cancer/breast/basic_info/index.htm#:~:text=Each%20year%20in%20the%20United,cancer%20than%20all%20other%20women.

⁵ American Cancer Society, *Breast Cancer HER2 Status*, <https://www.cancer.org/cancer/types/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-her2-status.html>



Between fifteen and twenty percent of breast cancer tumors will contain the HER2 protein.⁶ To most effectively treat breast cancer with HER2, patients require access to treatments that target the HER2 protein within the cancer.⁷ HER2 positive treatments will not effectively treat HER2-negative breast cancers.⁸

Similar to HER2 negativity and positivity, determining if the cancer is hormone receptor-positive or negative is also critical to selecting the appropriate treatment for a patient.⁹ If the cancer is hormone receptor-positive, it means that either estrogen or progesterone is contributing to the tumor's growth. Approximately 3 out of 4 cancers will be hormone receptor-positive.¹⁰ Hormone receptor-positive cancers can be treated by reducing the body's hormone production to slow the growth of the cancer cells.¹¹

Ultimately, understanding the complexities in cancer types, sizes, and severity can feel overwhelming for patients. Therefore, individuals rely on their trusted health care providers' expertise to ensure they have access to the most effective and appropriate treatment for their specific type of cancer.

II. UnitedHealthcare Step Therapy Policy on CDK4/6

CDK4/6 treatments are a type of cancer treatment that interrupts the growth of cancer cells within the body by targeting hormone receptor-positive and HER2-negative cancers.¹² Currently, three medications are Food and Drug Administration (FDA) approved CDK4/6 treatments.¹³ The National Comprehensive Cancer Network (NCCN) recommends CDK4/6 be used as a first line treatment for patients with hormone receptor-positive, HER2-negative breast cancer.¹⁴ NCCN does not prioritize one CDK4/6 treatment over another, as it recognizes that each patient's cancer is different and may require a different type of CDK4/6 treatment.

Despite clinical guidelines not distinguishing between these treatments, UnitedHealthcare has imposed a double-step step therapy policy for CDK4/6 treatments.¹⁵ Step therapy requires patients with breast cancer to try and fail on alternative treatments before the plan will cover the originally prescribed treatment. This approach can be dangerous for all patients, especially those

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ American Cancer Society, *Breast Cancer Hormone Receptor Status*, <https://www.cancer.org/cancer/types/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-hormone-receptor-status.html>

¹⁰ *Id.*

¹¹ *Id.*

¹² Susan G. Komen, *CDK4/6 Inhibitors*, <https://www.komen.org/breast-cancer/treatment/type/cdk4-6-inhibitors/#:~:text=What%20are%20CDK4%2F6%20inhibitors.to%20treat%20some%20breast%20cancers.>

¹³ *Id.*

¹⁴ NCCN, *Metastatic Breast Cancer*, https://www.nccn.org/patients/guidelines/content/PDF/stage_iv_breast-patient.pdf

¹⁵ UnitedHealthcare, *UnitedHealthcare Pharmacy Clinical Pharmacy Programs*, <https://www.uhcprovider.com/content/dam/provider/docs/public/resources/pharmacy/step-therapy/Step-Therapy-Kisqali.pdf>



with cancer, who may experience disease progression or even death if they are unable to promptly access the recommended treatment.¹⁶

UnitedHealthcare's 2023 policy requires patients to try and fail on both alternative CDK4/6 treatments before the health plan will cover the third available CDK4/6 treatment. Requiring patients to try and fail on two different treatments before covering the originally prescribed treatment means a patient's condition will continue to unnecessarily progress before the plan will cover the originally prescribed treatment.

Health care providers treating patients with breast cancer are much more familiar with the differences between CDK4/6 treatments, and therefore, have a better understanding of which treatment is most appropriate for each individual given their cancer, lifestyle, side effects, and other considerations. However, by imposing a two-step policy, the health care provider's judgement, discretion, and expertise are disregarded, and patients are forced to experience ongoing symptoms without relief, ultimately contributing to progression of the disease.

Therefore, to ensure patients with breast cancer have prompt access to their treatments, we urge UnitedHealthcare to revise and remove its double step-therapy policy for CDK4/6 treatments and ensure patients with breast cancer have equal access to all CDK4/6 treatments.

III. Conclusion

We appreciate your time in considering our concerns, and we urge you to swiftly remove barriers to accessing all CDK4/6 for patients with breast cancer. Please contact us at policy@aimedalliance.org if you would like to discuss any of our concerns.

Sincerely,

Ashira Vantrees
Counsel

¹⁶ Aimed Alliance, *Step Therapy*, <https://aimedalliance.org/step-therapy/>.