In 2014, olaparib became the first PARP inhibitor approved by the FDA. PARP inhibitors are a type of targeted oral cancer treatment that help keep cancer cells from repairing damaged DNA, causing them to die. Olaparib was initially granted accelerated approval for patients with advanced ovarian cancer who had already exhausted many treatment options and whose cancer tested positive for a BRCA mutation. Continued development of this targeted cancer medicine has led to various additional indications in breast, ovarian, pancreatic, and prostate cancers and a dosing reformulation to improve patient convenience. Olaparib has earned approval as maintenance therapy for some cancers, which is given to patients to help keep cancer from coming back after initial therapy. Research has also revealed significant survival benefits that could not have been known until years after initial approval.

**Additional Indication (August 2017):** Approved as maintenance therapy for patients with recurrent advanced ovarian cancer**, who have a response to chemotherapy, regardless of BRCA mutation status. As recurrence rates in ovarian cancer patients are high, maintenance therapies are used to help prevent and extend the time until recurrence following surgery or positive response to chemotherapy. In a clinical study, patients treated with olaparib were 27% more likely to be alive compared to patients taking no maintenance therapy. A high proportion of patients diagnosed with ovarian cancer already have later stage disease. As this type of cancer is a leading cause of cancer death in women, the availability of treatment options that can help extend survival in these patients is critically important.

**Dosing Reformulation (August 2017):** Approved dosing reformulation switched the daily dosing regimen from many capsules twice per day to two tablets twice per day, improving patient convenience.

**Additional Indication (January 2018):** Approved for patients with BRCA-mutated, HER2-negative metastatic breast cancer previously treated with chemotherapy. Olaparib was the first PARP inhibitor approved to treat this aggressive, difficult-to-treat cancer. In a clinical study, the therapy was shown to reduce risk of disease progression or death by 42% compared to standard of care chemotherapy.

**Earlier Treatment Line (December 2018):** Approved as a first-line maintenance therapy for patients with BRCA-mutated advanced ovarian cancer** who responded to chemotherapy. The BRCA gene mutation is present in up to 15% of all ovarian cancer cases. In a clinical trial, patients treated with olaparib were 70% more likely to live without their cancer getting worse compared to patients taking no maintenance therapy.

**Additional Indication (December 2019):** Approved as a first-line maintenance therapy for patients with metastatic pancreatic cancer whose cancer tested positive for a BRCA mutation and whose disease has not progressed on chemotherapy. In a clinical study, olaparib nearly doubled the time patients lived without their cancer getting worse. Pancreatic cancer has the lowest survival rate among the most common cancers, making treatments that can extend survival critical for patients with this disease.

**Use In Combination (May 2020):** Approved in combination with bevacizumab as a first-line maintenance treatment for patients with HRD-positive advanced ovarian cancer**, in combination with bevacizumab (maintenance therapy, first-line).
**Additional Indication (May 2020):** Approved to treat patients with a specific type of metastatic prostate cancer whose disease progressed after treatment with another medication. In a clinical study, patients treated with olaparib were 31% more likely to be alive compared to patients treated with another medication.\(^{13}\)

**Earlier Disease Stage (March 2022):** Approved for the adjuvant treatment of patients with a specific high-risk early breast cancer (BRCA-mutated HER2-negative) after treatment with chemotherapy. In a clinical study, olaparib demonstrated a meaningful survival benefit, reducing the risk of death by 32% compared to placebo.\(^{16}\)

**Additional Value Demonstrated in Approved Indication (September 2022):** Long-term follow up data showed improvement in survival for patients with BRCA-mutated advanced ovarian cancer who were treated with olaparib as first-line maintenance therapy. A clinical study showed that a majority of patients taking olaparib were alive after seven years, which marked the longest follow-up for any PARP inhibitor in this setting. Given the high mortality rate associated with ovarian cancer, this demonstration of long-term survival benefit marked a critically important advance for these patients.\(^{17}\)

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