“Fail-first” Step Therapy
Community Oncology Alliance Position Statement

**Community Oncology Alliance Position:**
The Community Oncology Alliance (COA) strongly opposes the use of “fail-first” step therapy for patients with cancer and other serious diseases because it puts the health of patients in jeopardy by delaying treatment with the physician preferred first and best therapy choice.

**Background:**
In many cases, patients with cancer will no longer have guaranteed access to potentially life-saving drugs. Instead, they will be subjected to “fail-first” step therapy and formulary restrictions that potentially prevent them from receiving the evidence-based therapies that their trained physicians prescribe as first-line cancer treatment.

Fail-first step therapy forces patients and their physicians to try cheaper, often older, treatments before they are allowed access to state-of-the-art, newer therapies, which are often more expensive. This is despite the recommendation of the treating physician who believes the cheaper treatment would not work.

Fail-first step therapy for cancer treatment is a dangerous step towards middlemen - health plans and pharmacy benefit managers (PBMs) - not oncologists, dictating which treatments patients with cancer can or cannot receive. This process subjects patients with cancer to delays and even denials of the evidence-based, individualized treatments that their oncologists prescribe.

Fail-first step therapy requirements is driven by financial interests and not by patients’ medical needs. This can leave patients at the whim of middlemen who are making treatment decisions to control costs or maximize profits rather than to maximize patient outcomes and well-being. Placing medical decision making in the hands of middlemen can force use of older, less appropriate, or less tolerable cancer treatment or drugs simply because of cost and profit margins.

For patients with cancer, fail-first step therapy can not only delay the delivery of the care prescribed by their oncologists, but also leaves patients facing this life-threatening disease without access to the most immediate and life-saving treatments. Although any fail-first step therapy requirement may attempt built-in protections and an appeals process for patients who are stopped from getting the most immediate and appropriate cancer treatment, navigating those hurdles while dealing with cancer can be agonizing to the patient, to providers, and is an unnecessary burden.

Allowing middlemen to influence treatment decisions is particularly dangerous in cancer care because there are few therapeutic and generic-to-brand substitutes and, unlike hypertension or diabetes, the wrong choice as initial therapy can be life-threatening. Patients need uninhibited access to the therapies their oncologists prescribe.
Summary:

COA believes that “fail-first” step therapy results in patients with cancer facing unnecessary delays or denials in accessing the specific individualized treatments their physicians have prescribed. Patients on fail-first step therapy are forced to receive potentially inferior or incorrect treatment options that their treating physicians considered and specifically did not prescribe. Fail-first step therapy programs insert third party middlemen, such as insurers and pharmacy benefit managers (PBMs), between patients and their treating physicians. The intervention by any third party can have a negative impact on patient outcomes, the physician-patient relationship, and the administrative burdens of cancer care, all of which we should be seeking to improve, not worsen.

Date:

Approved by the Board of Directors of COA on September 16, 2019.