New Cancer Drugs:

Important FDA Programs and Words to Know

Here's what to know about how drugs to treat cancer are approved by the U.S. Food and Drug Administration (FDA).

FDA APPROVAL

The drug has been approved by the FDA to treat a certain type of cancer in the specific use described on the drug's label. FDA approval is based on scientific evidence from clinical trials showing that the drug is safe and effective.

INVESTIGATIONAL DRUG

A drug that is not yet approved by the FDA and is still being studied in clinical trials.

EXPANDED ACCESS PROGRAMS

Also called compassionate use programs, these help patients with serious illnesses get access to drugs not yet approved by the FDA. Your doctor applies to the FDA and the drug manufacturer for access to the drug and for guidance and permission on how to give it. Approval by an institutional review board (IRB) is also required. The FDA approves about 99% of these requests.

RIGHT TO TRY

This 2018 law allows people with life-threatening illnesses the right to request access to investigational drugs directly from the manufacturer without FDA involvement, if they have tried all other available treatment options. The drug manufacturer must be willing to provide the drug for use by the patient.

DRUG EXCEPTION PROCESS

If the drug is FDA approved but not covered by your insurance, your doctor may contact your insurer directly to request coverage. They must describe how the drug is the best treatment option for your cancer.

OFF-LABEL USE

A doctor prescribes the drug for use outside of its FDA-approved use. The decision to use a drug off-label must be based on scientific evidence.

It's important to always talk with your doctor about your treatment plan and whether a new drug may fit into it. Visit cancer.net/FDAapproval for more information. Or, read this article in *JCO Oncology Practice*, "Determining If a Somatic Tumor Mutation Is Targetable and Options for Accessing Targeted Therapies."

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