

# Outlook on oncology 2024

Updates on some of the most  
cutting-edge trends in oncology  
from Optum Specialty Pharmacy



**Optum**

# Introduction

New innovations in both technology and medicine offer patients more options – both at home and at dedicated oncology treatment sites. Optum® Specialty Pharmacy is committed to keeping our pulse on all the groundbreaking trends in oncology. To that end, our oncology experts compiled these predictions based on in-depth analysis of the current oncology marketplace as well as deep industry research.

**This document highlights several key trends that will shape oncology in 2024:**

- 1** The need to balance the expansion of new medication approvals with access and ongoing medication shortages
- 2** Groundbreaking precision medications that require a new approach to personalized oncology care
- 3** Digital care options mean effective oncology treatment has the flexibility to extend beyond a physical location
- 4** New focused strategies to lower costs while providing affordable treatment options are redefining full-spectrum support

**Let's explore these trends further.**

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## #1: Balancing the expansion of new medications with access

Due in large part to advances in prevention, early detection and treatment, the age-adjusted overall oncology death rate in the U.S. fell by 33% between 1991 and 2020 – with an estimated 3.8 million oncology deaths averted. The number of oncology survivors in total in the U.S. is predicted to grow to around 20.3 million by 2026.<sup>1</sup>

In addition, new oncology medication approvals continue to accelerate. The U.S. Food & Drug Administration (FDA)'s Center for Drug Evaluation and Research (CDER) licensed 56 novel treatments in 2023; oncology was the most common therapeutic area to win CDER approvals this year, accounting for 31% of total new authorizations.<sup>2</sup>

## Novel medication approvals in oncology 2023<sup>3</sup>

Brand name	Generic name	Indications
Jaypirca <sup>®</sup>	pirtobrutinib	Relapsed or refractory mantle cell lymphoma in adults who have had at least two lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor
Orserdu <sup>®</sup>	elacestrant	Estrogen receptor-positive, human epidermal growth factor receptor 2-negative, ESR1-mutated, advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy
Zynyz <sup>®</sup>	retifanlimab-dlwr	Metastatic or recurrent locally advanced Merkel cell carcinoma
Epkinly <sup>®</sup>	epcoritamab-bysp	Relapsed or refractory diffuse large B-cell lymphoma (not otherwise specified) and high-grade B-cell lymphoma after two or more lines of systemic therapy
Columvi <sup>®</sup>	glofitamab-gxbm	Diffuse large B-cell lymphoma, not otherwise specified, or large B-cell lymphoma arising from follicular lymphoma after two or more lines of systemic therapy
Vanflyta <sup>®</sup>	quizartinib	To use as part of a treatment regimen for newly diagnosed acute myeloid leukemia that meets certain criteria
Talvey <sup>®</sup>	talquetamab-tgvs	Relapsed or refractory multiple myeloma after at least four prior therapies
Elrexio <sup>®</sup>	elranatamab-bcmm	Relapsed or refractory multiple myeloma after at least four prior lines of therapy
Logtorzi <sup>®</sup>	toripalimab-tpzi	Recurrent or metastatic nasopharyngeal carcinoma when used together with or following other therapies
Fruzagla <sup>®</sup>	fruquintinib	Refractory, metastatic colorectal cancer
Augtyro <sup>®</sup>	repotrectinib	ROS1-positive non-small cell lung cancer
Truqap <sup>®</sup>	capivasertib	To treat breast cancer that meets certain disease criteria



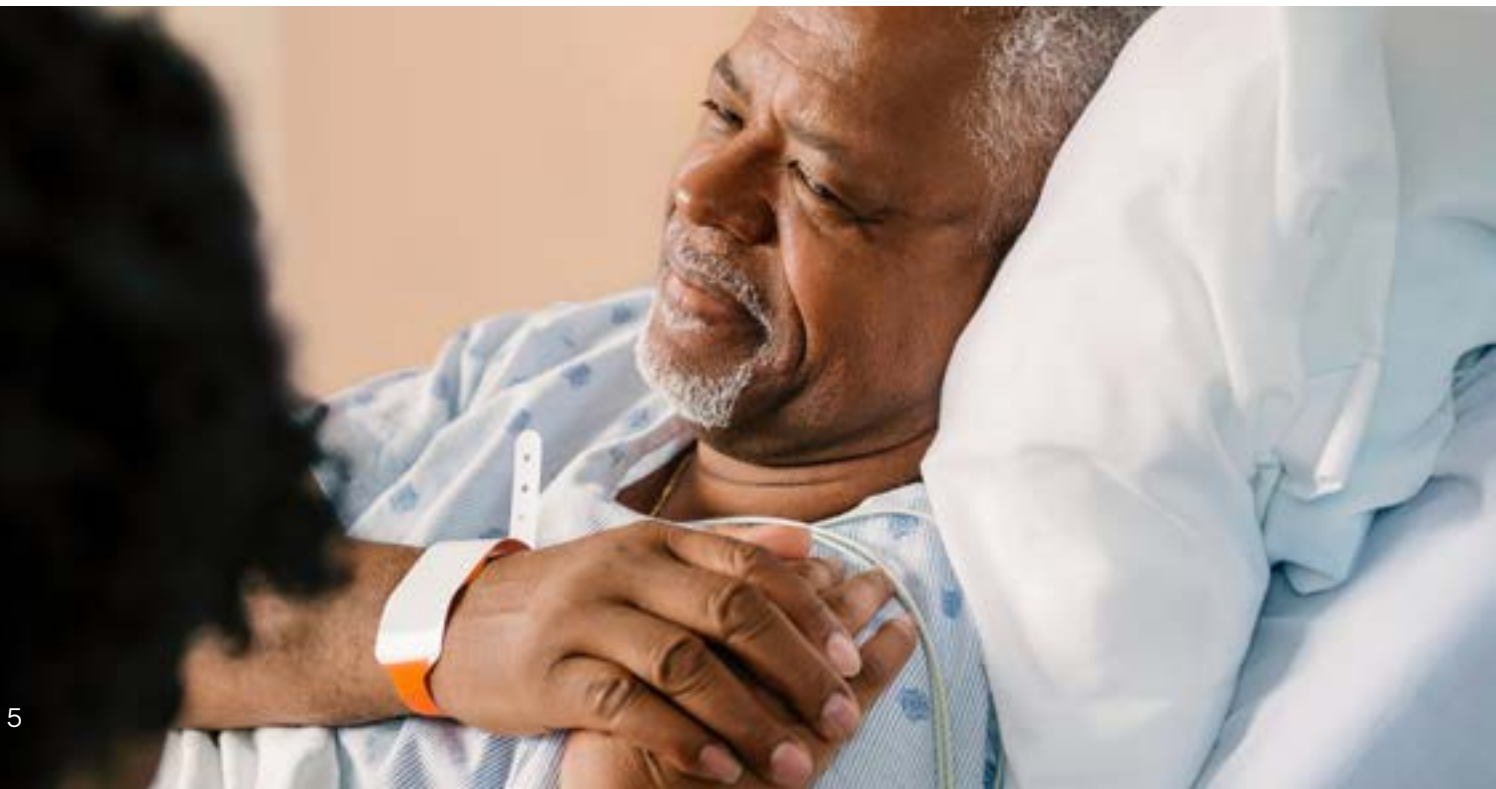
But even with the promising decline in deaths and upsurge of novel treatments, the American Cancer Society estimated almost two million new cancer cases in the United States in 2024.<sup>4</sup> Younger patients are being diagnosed with cancer in rates previously unseen. This number will increase significantly in the years to come due to advances in cancer screening and detection.<sup>5</sup> To compound this surge in younger patients, ongoing and active medication shortages are the highest in a decade. Nearly every major U.S. cancer center reported in surveys that they faced chemotherapy shortfalls last spring and summer.<sup>6</sup>

Medication shortages can occur for many reasons, including manufacturing and quality problems, delays and discontinuations. The permanent closure of a U.S.-based factory and a natural disaster at another U.S.-based factory have worsened shortages.<sup>7</sup> Those shortages directly affect patient care. One survey found that nearly 60 percent of more than 1,000 pharmacy respondents deemed chemotherapy medication shortages “critically impactful.”<sup>8</sup>

This presents a dilemma: what to do? Shortages of chemotherapy medications driven by poor manufacturing quality are resulting in rationing

of care in some cases.<sup>9</sup> While the majority of oncology medication shortages have been those intravenously administered, oral oncolytics have also been affected. Low supply of anticancer medications results in difficult decisions about how to treat patients, including rationing doses or turning to other treatment options with potentially less efficacy. In order to avoid disruptions in oncology treatment plans, it is essential to carefully manage and monitor medication supply chains.

Providing patients with access to the oncology therapies they need is critical – especially as the industry tries to balance a surge of new therapies with medication shortages. It makes sense that oncologists will want to partner with organizations, including specialty pharmacies with diverse purchasing capabilities, that can help them get the specialty treatments and limited-distribution drugs they need, when their patients need them. Using a robust specialty pharmacy in lieu of local and limited distribution and dispensing agents can limit disruptions to patient care and support optimal outcomes.



## #2: Precision medication with a nuanced approach

The advent of precision medicine has changed the landscape of oncologic biomarkers, medication discovery, medication development and patient outcomes for the foreseeable future. Precision oncology involves the genomic profiling of tumors to detect medically actionable variations. Advances in clinical next-generation sequencing (NGS) from both tumor tissue and liquid biopsy and the availability of targeted therapies continues to dominate mainstream clinical practice.

Since 2011, the FDA has approved 11 immune checkpoint inhibitors, which release “brakes” on the surface of certain immune cells that help T cells destroy cancer cells. Many of these medications are approved for more than one type of cancer, making immune checkpoint inhibitors a treatment option for more than 20 cancer types and tumors with certain specific molecular characteristics. In addition, the FDA has approved multiple chimeric antigen receptor (CAR) T-cell therapies to treat a range of hematologic malignancies since 2017.<sup>10</sup> CAR T-cell therapy is a type of adoptive cell therapy, which is designed to dramatically increase the number of a person’s cancer-killing immune cells. It’s anticipated that wider use of novel immunotherapies and CAR T-cell therapies will also grow in the next five years, providing patients with additional benefits and options.

Advances in precision oncology enabled the development of multiple novel therapies and combinations in 2023. **Twelve novel treatments** were approved by the FDA for unique biomarker-selected indications, and six new biomarker- and indication-specific treatments were listed in the National Comprehensive Cancer Network (NCCN) guidelines in the past year.<sup>11</sup>

The continued emergence of targeted medication helps doctors personalize treatment for their patients. For example, elacestrant, a next-generation selective estrogen receptor degrader, received FDA approval in 2023 for patients with estrogen receptor (ER)-positive, endocrine therapy-refractory, human epidermal growth factor receptor-2 (HER2)-negative breast cancer with an estrogen receptor gene (ESR1) mutation.<sup>12</sup> ESR1 mutations have been associated with resistance to hormone therapy, due in part to estrogen independent signaling. Elacestrant is a novel oral selective estrogen receptor degrader (SERD) that selectively binds to the estrogen receptor in breast cancer cells, inhibiting tumor growth.<sup>13</sup> As new biomarkers are discovered, opportunities to tailor treatment regimens to each patient across a variety of cancers and develop new medication targets will continue to increase.



## Updates in the oncology precision medicine landscape 2023<sup>14</sup>

Molecular biomarker	Cancer type	Generic medication name
<b>Biomarkers listed in the tumor type-specific “Indications and Usage” section in the FDA medication label</b>		
<i>ERBB2</i> amplification	Colorectal cancer	tucatinib + trastuzumab
ESR1 oncogenic ligand-binding domain missense mutations	Breast cancer	elacestrant
BRAF <sup>V600E</sup>	Low-grade glioma (pediatric)	dabrafenib + trametinib
ATM, ATR, CDK12, CHEK2, FANCA, MLH1, MRE11, NBN, PALB2, RAD51C oncogenic mutations	Prostate cancer	talazoparib + enzalutamide
BRCA1/2 oncogenic mutations	Prostate cancer	talazoparib + enzalutamide olaparib + abiraterone + prednisone niraparib + abiraterone acetate + prednisone
FLT3 internal tandem duplication	Acute myeloid leukemia	quizartinib
Microsatellite instability-high	Endometrial cancer	dostarlimab + carboplatin + paclitaxel
BRAF <sup>V600E</sup>	Non-small cell lung cancer	encorafenib + binimetinib
IDH1 R132	Myelodysplastic syndrome	ivosidenib
ROS1 fusions	Non-small cell lung cancer	repotrectinib
PIK3CA, AKT1 or PTEN oncogenic mutations	Breast cancer	capivasertib + fulvestrant
<b>Biomarkers listed in the treatment recommendations section of a tumor type-specific NCCN guideline</b>		
KRAS <sup>G12C</sup>	Pancreatic adenocarcinoma	adagrasib, sotorasib
ESR1 oncogenic ligand-binding domain in-frame insertions or deletions	Breast cancer	elacestrant
ERBB2 amplification	Biliary tract cancer	trastuzumab + pertuzumab
ALK fusions	Inflammatory myofibroblastic tumors	alectinib
IDH1 oncogenic mutations	Oligodendroglioma	ivosidenib
KRAS <sup>G12C</sup>	Colorectal and rectal cancer	(sotorasib or adagrasib) + (cetuximab or panitumumab)

Other notable recent advances include gene editing, to develop more effective versions of adoptive cell therapy for treatment of solid tumors and developing messenger RNA (mRNA)-based vaccines and therapeutics to treat cancer, among many other innovative approaches.<sup>15</sup>

Based on the current pipeline, more than 100 new oncology medications are anticipated, with biomarker-driven therapies becoming more common. Finally, NGS, which can test for multiple potential mutations at once and more precisely guide therapy selection, are expected to increase as well. Looking ahead, these exciting new therapies allow oncologists to provide truly personalized treatments based on each individual patient's own genetic makeup.

The increasing complexity of oncology care, combined with the momentum of new biosimilar and novel medication approvals require a specialty pharmacy oncology team who will provide an extra layer of support throughout the patient journey – for both patients and their providers. To stay on top of these advances requires nuanced approaches and cancer-specific clinical monitoring programs, designed and led by board-certified oncology pharmacists.

### #3: Oncology care without walls

A cancer diagnosis doesn't necessarily mean multiple trips to a physical building for treatment. The pandemic required creative solutions to the challenges of limiting contact and decreasing infection risk, especially for patients with lowered immune system response from cancer treatments. Those creative solutions continue to be used in oncology care.

Telehealth gives people the flexibility to access care when it is convenient. One study showed virtual care was preferred over in-person care during the pandemic. Assessing the experience with telemedicine and in-person visits among individuals with cancer, almost 76% of cancer patients were highly satisfied with access to doctors via televisits, compared with about 63% of those who saw their doctors in person. About 91% of people who saw their doctor virtually were highly satisfied with the response and amount of concern their doctor expressed. By contrast, just over 84% of people who saw their doctor in person felt this way.<sup>16</sup>

In addition, compared with in-person visits, telehealth may save people living with cancer time, travel and money. According to cost models at one cancer center, telehealth was associated with nearly \$1.2 million savings in otherwise lost income due to driving time and \$467,000 savings in lost income due to visit time. That results in a total estimated savings in lost income of \$1.6 million across the 11,600 participants with cancer and younger than age 65 who participated in the study.<sup>17</sup>

Many online medical networks offer round-the-clock access to specialists and support services. At-home monitoring tools that transmit readings to medical professionals can signal new symptoms, worsening health, and potential emergencies. This can help people get fast interventions, which may be lifesaving.<sup>18</sup>

Adopting digital health options benefits providers and patients alike. While certain patients and clinical scenarios still require in-person care, virtual care enhancements can be used to address pre-existing challenges oncologists face in communities across the country. For example, caring for cancer patients who live many miles away from a hospital or clinic and without the robust support services seen at larger treatment centers. Routine follow ups and treatment toxicity monitoring can be coordinated by implementing remote clinical management programs, focusing on adherence and adverse effect prevention and management.



The move to digital care means in-depth clinical management from multidisciplinary, oncology-specific units that provide the full care cycle. Provider and patient portals make it easier to coordinate and manage treatment online. Provider offices relay supply orders, automate administrative duties and integrate patient records through electronic medical records (EMR) system connections to pharmacies to make care easier. Building out accessible virtual health care services for every step of the cancer patient journey will be crucial moving forward as the nation works towards digital health equity.

Using technology to facilitate a seamless experience should be the hallmark of a specialty pharmacy service. Digital tools can help streamline the entire process from prescription to shipment as well as ongoing clinical monitoring. With the move to more sophisticated digital experiences, many providers prefer to work with a specialty pharmacy that offers a best-in-class digital experience for website, portals and mobile apps.<sup>19</sup> In addition, online access to clinical management programs with deep expertise in oncology care will need to be at the forefront of this new chapter in telehealth to modernize patient care.

#### #4: The challenging costs of oncology care

For many patients, the rising costs of oncology treatment will be a barrier to care. While spending on oncology medications in the United States is anticipated to reach \$125 billion by 2027, overall drug savings of more than \$180 billion are also expected as newly approved biosimilars launch, and existing biosimilars see continued uptake and price reductions.<sup>20</sup>

Many are hopeful that biosimilars can help curb costs.<sup>21</sup> A biosimilar is a biological medicine highly similar to another already approved biological medicine, referred to as the reference product. Biosimilars are approved according to the same standards of pharmaceutical quality, safety and efficacy applied to all biological medicines. The adoption and potential of biosimilars to manage rising drug costs is widely recognized; the prices of biosimilars on average can be up to 50% lower than the reference products.<sup>22</sup>

This is for two reasons. First, using a synthetic version makes the source material less expensive. Secondly, the regulatory pathway for biologics is much easier than for the original medication, so manufacturers aren't trying to recoup years and years of research time.



# Oncology biosimilars approved from 2022–2023<sup>23</sup>

Biosimilar name	Approval date	Reference product
<b>Udenyca<sup>®</sup></b> <b>(pegfilgrastim-cbqv)</b>	December 2023	Neulasta <sup>®</sup> Onpro <sup>®</sup> (pegfilgrastim with on-body injector)
<b>Avzivi<sup>®</sup></b> <b>(bevacizumab-tnjn)</b>	December 2023	Avastin <sup>®</sup> (bevacizumab)
<b>Vegzelma<sup>®</sup></b> <b>(bevacizumab-adcd)</b>	September 2022	Avastin (bevacizumab)
<b>Stimufend<sup>®</sup></b> <b>(pegfilgrastim-fpgk)</b>	September 2022	Neulasta (pegfilgrastim)
<b>Fylnetra<sup>®</sup></b> <b>(pegfilgrastim-pbbk)</b>	May 2022	Neulasta (pegfilgrastim)
<b>Alymsys<sup>®</sup></b> <b>(bevacizumab-maly)</b>	April 2022	Avastin (bevacizumab)
<b>Releuko<sup>®</sup></b> <b>(filgrastim-ayow)</b>	February 2022	Neupogen <sup>®</sup> (filgrastim)

Navigating these new options and determining the best care for each patient can be overwhelming. In response, oncology specialty pharmacies need to continue to develop unique programs and services to support patient-based medication utilization plans, optimal oncology therapy selection and maximized cost-management outcomes. Specialty pharmacies that offer comprehensive support improves access to care and supports guideline-concordant treatment. Better understanding and navigating those processes increase provider and patient satisfaction and ultimately improves outcomes and enhances health equity.

There will be increased demand for these solutions and support services, especially with the introduction of more biosimilars, new immunotherapies, cellular therapies and gene treatments with multi-million-dollar price tags. For example, approval of the first treatment derived from CRISPR, the revolutionary gene-editing method and treatment intended to cure sickle-cell disease and a related condition, beta thalassemia, is expected to cost millions of dollars per patient.<sup>24</sup> Growth of the U.S.

biosimilars market promises alternatives to many branded biologic medications and helps provide choice and clinically effective care at lower costs. As part of the Inflation Reduction Act of 2022, recent implementation of Medicare payment changes for certain biosimilars provides a payment increase for qualifying biosimilars to foster competition in the drug marketplace.<sup>25</sup>

Proactive financial assistance programs that identify all available resources for patients are crucial. Some patients may not be aware of the financial assistance options available to them, or they may feel reluctant to ask for help.

To fundamentally change how a patient is able to access care, specialty pharmacies are implementing proactive technology that automatically identifies financial resources for patients along with a robust team with expertise in manufacturer copay card enrollment, cancer foundation grant options and financial-based assistance.

## How these trends redefine specialty treatment support

With multifaceted anticancer treatments, access to care issues and financial realities, it's important to find a partner that offers solutions and experts who understand this complicated arena.

- 1. Balancing the expansion of new medications with access.** In addition to accessing limited-distribution oncology medications, specialty pharmacies should offer personalized services such as financial assistance sourcing, expert clinical counseling, insurance benefit verification and digital tools. Board-certified oncology pharmacists and dedicated patient care support teams guide patients with compassion along their cancer journey.
- 2. Precision medication with a nuanced approach.** Designated specialty pharmacists have specialized oncology training to support physicians in designing, implementing, monitoring and modifying pharmacotherapeutic treatments; helping to manage adverse events or clinical situations associated with cancer and cancer therapies.<sup>26</sup>
- 3. Oncology care without walls.** Personalized treatments from dedicated specialty pharmacy patient care coordinators can help provide high-level coordinated support for oncology patients managing their conditions. A clinical monitoring program with a holistic approach can provide continuity of care throughout the patient's entire treatment journey and improve quality of life for patients as well as their caregivers.
- 4. The challenging costs of oncology care.** There is a need for comprehensive support that improves patient access to care and financial assistance as well as supports guideline-concordant treatment. These innovations must also tailor options for patients based on their needs and preferences. All with the goal of helping patients access affordable care, reduce their financial burden, improve their satisfaction and reduce delays in care.



## Optum Oncology Center of Excellence

The Optum Oncology Center of Excellence – backed by board-certified oncology pharmacists – help physicians make informed treatment decisions using their robust clinical expertise. This in-depth clinical support frees up providers

and their practices to focus on what matters most – patient care. With the sharpening focus on value-based care, providers need a new set of tools to help deliver better patient outcomes.

### These are just some of the ways Optum Specialty Pharmacy helps



#### Accessibility

Everything we do centers on getting patients the therapy they need, when they need it, their way. With broad access to hundreds of oncology medications and the best access to limited-distribution drugs, we can support patients throughout their treatment even if they switch therapies. We are in network with most insurance providers and have a team of experts to help patients through the insurance and claims process.<sup>27</sup>



#### Affordability

Powered by Optum Savings IQ™, we connect patients in real-time with all the financial assistance options they need to start therapy without delay. This new and evolving technology embedded into our onboarding process helps find all available aid from all sources including foundation assistance, copay cards, vouchers, free drug programs and more. \$823.5 million in overall financial assistance was delivered to patients in 2023.<sup>28</sup>



#### Advocacy

The Optum Oncology Center of Excellence tailors support to help people manage the complexity that comes with each specific cancer diagnosis. Our personalized approach for patients includes clinical engagement and interventions, adherence tools that improve outcomes, a mobile app and patient portal. We also help streamline processes for providers with electronic medical record interoperability, appeals support and individualized communication preferences. And, they can chat live with a pharmacist via our provider portal.

## To refer your patient

Just e-prescribe or fax the patient's prescription to Optum Specialty Pharmacy.

### E-prescribe using this information:

1050 Patrol Road  
Jeffersonville, IN 47130

**NPI:** 1083045140

**NCPDP:** 1564930



### Fax:

1-877-342-4596



### Call:

1-855-215-0235



**Chat** live on our **provider portal** to connect with our clinical team

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To learn more about Optum Specialty Pharmacy oncology services, visit [optum.com/oncology](https://optum.com/oncology).

Pharmaceutical inquiries, contact us at [Specialty\\_and\\_Infusion\\_BusinessDevelopment@ds.uhc.com](mailto:Specialty_and_Infusion_BusinessDevelopment@ds.uhc.com)



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