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The Association of Community Cancer Centers (ACCC) is the leading advocacy and education organization for the multidisciplinary cancer care team. Approximately 20,000 cancer care professionals from 2,000 hospitals and practices nationwide are affiliated with ACCC. Providing a national forum for addressing issues that affect community cancer programs, ACCC is recognized as the premier provider of resources for the entire oncology care team. Our members include medical and radiation oncologists, surgeons, cancer program administrators and medical directors, senior hospital executives, practice managers, pharmacists, oncology nurses, radiation therapists, social workers, and cancer program data managers. Not a member? Join today at accc-cancer.org/membership or email membership@accc-cancer.org. For more information, visit the ACCC website at accc-cancer.org. Follow us on Facebook, Twitter, LinkedIn, and read our blog, ACCCBuzz.
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## Financial Toxicity

**A conversation with Yousuf Zafar, MD, MHS, and Dan Sherman, MA, LPC**

### Accessing Co-Pay Assistance Opportunities

**By Ann Kaley Kline**

### PAP Flow Chart

### PAP Quick Reference Guide

### Pharmaceutical Company Patient Assistance & Reimbursement Programs

<table>
<thead>
<tr>
<th>Company</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>AbbVie</td>
<td>26</td>
</tr>
<tr>
<td>Amgen, Inc.</td>
<td>27</td>
</tr>
<tr>
<td>ARIAD Pharmaceuticals, Inc.</td>
<td>30</td>
</tr>
<tr>
<td>Astellas Pharma US, Inc.</td>
<td>31</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>34</td>
</tr>
<tr>
<td>Bayer HealthCare Pharmaceuticals, Inc.</td>
<td>36</td>
</tr>
<tr>
<td>Boehringer Ingelheim Pharmaceuticals, Inc.</td>
<td>38</td>
</tr>
<tr>
<td>Bristol-Myers Squibb</td>
<td>41</td>
</tr>
<tr>
<td>Celgene Oncology</td>
<td>44</td>
</tr>
<tr>
<td>Eisai Co., Ltd.</td>
<td>47</td>
</tr>
<tr>
<td>Genentech, Inc.</td>
<td>49</td>
</tr>
<tr>
<td>Incyte Corporation</td>
<td>52</td>
</tr>
<tr>
<td>Insys Therapeutics, Inc.</td>
<td>54</td>
</tr>
<tr>
<td>IPSEN Biopharmaceuticals</td>
<td>55</td>
</tr>
<tr>
<td>Janssen Biotech, Inc.</td>
<td>57</td>
</tr>
<tr>
<td>Lilly Oncology</td>
<td>60</td>
</tr>
<tr>
<td>Merck</td>
<td>63</td>
</tr>
<tr>
<td>Merrimack Pharmaceuticals, Inc.</td>
<td>66</td>
</tr>
<tr>
<td>Novartis Pharmaceuticals Corporation</td>
<td>68</td>
</tr>
<tr>
<td>Pfizer, Inc.</td>
<td>71</td>
</tr>
<tr>
<td>Pharmacycics, LLC</td>
<td>75</td>
</tr>
<tr>
<td>Sandoz, Inc.</td>
<td>76</td>
</tr>
<tr>
<td>Sanofi Oncology</td>
<td>79</td>
</tr>
<tr>
<td>Seattle Genetics</td>
<td>80</td>
</tr>
<tr>
<td>Taiho Oncology</td>
<td>82</td>
</tr>
<tr>
<td>Takeda Oncology</td>
<td>83</td>
</tr>
<tr>
<td>Tesaro, Inc.</td>
<td>86</td>
</tr>
<tr>
<td>Teva Oncology</td>
<td>88</td>
</tr>
</tbody>
</table>

### Other Patient Assistance Programs & Resources

<table>
<thead>
<tr>
<th>Program</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agingcare.com®</td>
<td>90</td>
</tr>
<tr>
<td>BenefitsCheckUp®</td>
<td>90</td>
</tr>
<tr>
<td>CancerCare®</td>
<td>90</td>
</tr>
<tr>
<td>CancerCare® Co-Payment Assistance Foundation</td>
<td>91</td>
</tr>
<tr>
<td>Cancer Financial Assistance Coalition</td>
<td>92</td>
</tr>
<tr>
<td>Co-Pay Relief</td>
<td>92</td>
</tr>
<tr>
<td>Good Days</td>
<td>92</td>
</tr>
<tr>
<td>HealthWell Foundation</td>
<td>93</td>
</tr>
<tr>
<td>The Leukemia &amp; Lymphoma Society</td>
<td>94</td>
</tr>
<tr>
<td>NeedyMeds</td>
<td>94</td>
</tr>
<tr>
<td>Partnership for Prescription Assistance</td>
<td>95</td>
</tr>
<tr>
<td>Patient Access Network Foundation</td>
<td>96</td>
</tr>
<tr>
<td>Patient Advocate Foundation</td>
<td>97</td>
</tr>
<tr>
<td>RxAssist</td>
<td>98</td>
</tr>
<tr>
<td>RxHope™</td>
<td>99</td>
</tr>
<tr>
<td>Rx Outreach®</td>
<td>99</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Reimbursement Information</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td><strong>Abrafax®</strong> (paclitaxel protein-bound particles)</td>
<td>44</td>
</tr>
<tr>
<td><strong>Actiq®</strong> (oral transmucosal fentanyl citrate) [C-II]</td>
<td>88</td>
</tr>
<tr>
<td><strong>Ad cetir®</strong> (brentuximab vedotin) for injection</td>
<td>80</td>
</tr>
<tr>
<td><strong>Afinitor®</strong> (everolimus) tablets</td>
<td>68</td>
</tr>
<tr>
<td><strong>Akynzeo®</strong> (neupitrapalnizoidon)</td>
<td>47</td>
</tr>
<tr>
<td><strong>Alectona®</strong> (neramicin) capsules</td>
<td>49</td>
</tr>
<tr>
<td><strong>Alimta®</strong> (pemetrexed for injection)</td>
<td>60</td>
</tr>
<tr>
<td><strong>Alexi®</strong> (paroxetine) tablets</td>
<td>47</td>
</tr>
<tr>
<td><strong>Arnex®</strong> (darbepoetin alfa)</td>
<td>27</td>
</tr>
<tr>
<td><strong>Armide®</strong> (astrozople)</td>
<td>34</td>
</tr>
<tr>
<td><strong>Aromasin®</strong> (exemestane) tablets</td>
<td>71</td>
</tr>
<tr>
<td><strong>Arzerra®</strong> (ofatumumab) injection</td>
<td>68</td>
</tr>
<tr>
<td><strong>Avastin®</strong> (bevacizumab)</td>
<td>49</td>
</tr>
<tr>
<td><strong>Bendeka®</strong> (bendamustine hydrochloride) for injection</td>
<td>88</td>
</tr>
<tr>
<td>**Binycalo° (blinatumomab)</td>
<td>27</td>
</tr>
<tr>
<td><strong>Bosal®</strong> (bosutinib) tablets</td>
<td>71</td>
</tr>
<tr>
<td><strong>Campto®</strong> (intronatox) injection</td>
<td>71</td>
</tr>
<tr>
<td><strong>Carperla®</strong> (vandetanib) tablets</td>
<td>34</td>
</tr>
<tr>
<td><strong>Cetox®</strong> (bicalutamide)</td>
<td>49</td>
</tr>
<tr>
<td><strong>Cotellic®</strong> (cobimetinib) tablets</td>
<td>49</td>
</tr>
<tr>
<td><strong>Cyramza®</strong> (ramucirumab)</td>
<td>60</td>
</tr>
<tr>
<td><strong>Darzalex®</strong> (daratumumab)</td>
<td>57</td>
</tr>
<tr>
<td><strong>Doxil®</strong> (doxorubicin HCl liposome injection)</td>
<td>57</td>
</tr>
<tr>
<td>**Eloit® (elotuzumab)</td>
<td>41</td>
</tr>
<tr>
<td><strong>Empliciti®</strong> (elotuzumab)</td>
<td>63</td>
</tr>
<tr>
<td><strong>Emend®</strong> (aprepitant)</td>
<td>63</td>
</tr>
<tr>
<td><strong>Emend®</strong> (fosaprepitant dimethigumline) for injection</td>
<td>63</td>
</tr>
<tr>
<td><strong>Empliciti®</strong> (elotuzumab)</td>
<td>41</td>
</tr>
<tr>
<td><strong>Eoopen®</strong> (epoetin alfa)</td>
<td>27</td>
</tr>
<tr>
<td><strong>Ertibux®</strong> (etuxumab)</td>
<td>68</td>
</tr>
<tr>
<td><strong>Ervedge®</strong> (vismodegib)</td>
<td>78</td>
</tr>
<tr>
<td><strong>Eloxi®</strong> (oxaliplatin) for injection</td>
<td>78</td>
</tr>
<tr>
<td><strong>Emcyt®</strong> (estramustine phosphate sodium capsules)</td>
<td>71</td>
</tr>
<tr>
<td><strong>Emend®</strong> (aprepitant)</td>
<td>63</td>
</tr>
<tr>
<td><strong>Exjade®</strong> (deferasirox) tablets</td>
<td>68</td>
</tr>
<tr>
<td><strong>Facil®</strong> (folic acid)</td>
<td>71</td>
</tr>
<tr>
<td><strong>Fentora®</strong> (fentanyl buccal tablet) [C-II]</td>
<td>88</td>
</tr>
<tr>
<td>**Famatis® (famotidine) tablets</td>
<td>88</td>
</tr>
<tr>
<td>**Gardasi® (Quadrivalent Human Papillomavirus Recombinant Vaccine)</td>
<td>63</td>
</tr>
<tr>
<td>**Gardasil® (Human Papillomavirus 9-valent Vaccine, Recombinant)</td>
<td>63</td>
</tr>
<tr>
<td><strong>Gazyva®</strong> (obinutuzumab)</td>
<td>49</td>
</tr>
<tr>
<td><strong>Gemzar®</strong> (gemcitabine hydrochloride)</td>
<td>60</td>
</tr>
<tr>
<td><strong>Glotir®</strong> (afatinib)</td>
<td>38</td>
</tr>
<tr>
<td><strong>Gleevec®</strong> (imatinib mesylate) tablets</td>
<td>68</td>
</tr>
<tr>
<td><strong>Gilevec®</strong> (imatinib mesylate) capsules</td>
<td>68</td>
</tr>
<tr>
<td><strong>Fosaprepitant dimeglumine for injection</strong></td>
<td>63</td>
</tr>
<tr>
<td><strong>Fosaprepitant</strong> (aprepitant)</td>
<td>63</td>
</tr>
<tr>
<td><strong>Famatis®</strong> (famotidine) tablets</td>
<td>68</td>
</tr>
<tr>
<td><strong>Fentora®</strong> (fentanyl buccal tablet) [C-II]</td>
<td>88</td>
</tr>
<tr>
<td>**Gardasi® (Quadrivalent Human Papillomavirus Recombinant Vaccine)</td>
<td>63</td>
</tr>
<tr>
<td><strong>Gazyva®</strong> (obinutuzumab)</td>
<td>49</td>
</tr>
<tr>
<td><strong>Gemzar®</strong> (gemcitabine hydrochloride)</td>
<td>60</td>
</tr>
<tr>
<td><strong>Glotir®</strong> (afatinib)</td>
<td>38</td>
</tr>
<tr>
<td><strong>Gleevec®</strong> (imatinib mesylate) capsules</td>
<td>68</td>
</tr>
<tr>
<td><strong>Foral®</strong> (furfurylamine) injection</td>
<td>47</td>
</tr>
<tr>
<td><strong>Herceptin®</strong> (herceptin)</td>
<td>47</td>
</tr>
<tr>
<td><strong>Hexal®</strong> (albendazole) capsules</td>
<td>47</td>
</tr>
<tr>
<td>**Ibrocic® (pallbocibin)</td>
<td>71</td>
</tr>
<tr>
<td><strong>Iclusit®</strong> (pomatitinib)</td>
<td>30</td>
</tr>
<tr>
<td>**Idamcy® (idarubicin hydrochloride) for injection</td>
<td>71</td>
</tr>
<tr>
<td><strong>Imbruvica®</strong> (ibrutinib)</td>
<td>78</td>
</tr>
<tr>
<td><strong>Imlygic®</strong> (talimogene laherparepvec)</td>
<td>27</td>
</tr>
<tr>
<td><strong>Imply®</strong> (tarceva)</td>
<td>88</td>
</tr>
<tr>
<td><strong>Intron® A</strong> (interferon alfa-2b, recombinant) for injection</td>
<td>63</td>
</tr>
<tr>
<td><strong>Iressa®</strong> (gefitinib)</td>
<td>34</td>
</tr>
<tr>
<td>**Jadenu® (idefbrarvore) tablets</td>
<td>78</td>
</tr>
<tr>
<td>**Jaka® (poxilolnib) tablets</td>
<td>52</td>
</tr>
<tr>
<td>**Jevilana® (cabazitaxel)</td>
<td>78</td>
</tr>
<tr>
<td><strong>Kadcyla®</strong> (ado-trastuzumab emtansine)</td>
<td>49</td>
</tr>
<tr>
<td>**Krytriva® (pembrolimumab)</td>
<td>65</td>
</tr>
<tr>
<td><strong>Kyprolis®</strong> (carfilzomib) for injection</td>
<td>47</td>
</tr>
<tr>
<td>**Levina® (levatinib) capsules</td>
<td>57</td>
</tr>
<tr>
<td>**Leukine® (sargramostim)</td>
<td>78</td>
</tr>
</tbody>
</table>
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A conversation with Yousuf Zafar, MD, MHS, and Dan Sherman, MA, LPC

Financial Toxicity:
Awareness has grown among both the public and providers about the risks of financial toxicity for patients with cancer and their families. At the same time, as healthcare reform evolves, understanding the financial implications of care has become increasingly complex. ACCC asked members of the Financial Advocacy Network (FAN) Advisory Committee Yousuf Zafar, MD, MHS, associate professor of Medicine, Duke Cancer Institute, and Dan Sherman, MA, LPC, clinical financial consultant, The Lacks Cancer Center, to share their perspectives on why addressing financial concerns with cancer patients is important and how the role of financial counselors is evolving.

Why is it important that we do a better job of helping patients with financial issues related to their cancer treatments?

Dr. Zafar. My primary goal is to make sure that any treatment I provide a patient first does no harm. Traditionally, we’ve thought about harm as physical harm, the physical side effects that patients can experience as a result of treatment. More and more, however, financial harm has to be a part of that consideration as well. So as an oncologist, if I’m prescribing a treatment for a patient, considering both the potential for physical and financial harms is well within my purview.

How do you think providers can do a better job in this area?

Dr. Zafar. I think the first step is engaging patients on the topic. There is evidence that just discussing financial harm or financial toxicity with their doctor can reduce the distress that patients feel. So really what this means is that patients like to know that they and their doctor are on the same page when it comes to what the patient is experiencing. That’s the first step. The second is being aware of the resources around us that can help. As an oncologist I don’t think my job is to know how
A conversation with Yousuf Zafar, MD, MHS, and Dan Sherman, MA, LPC

Financial Toxicity: much every MRI or every drug I prescribe is going to cost, but I should know where I can go for help. So understanding that I need to involve my colleagues that I work with—my pharmacists, social workers, and financial counselors—and know where those resources are to direct patients to when they ask is very important.

Dan, from the financial navigator’s perspective, why is it important to do a better job helping patients with these issues?

Dan Sherman. Improvement in this area is needed because of what Dr. Zafar and researchers like him are finding regarding the alarming statistics of financial toxicity. We now know that financial toxicity and related anxiety are the top concern of oncology patients. The main concern is no longer dying from the disease; it’s the financial worries that consume our patients. This financial toxicity also creates a barrier in providing care and unfortunately patients refuse the recommended treatments because we have failed the patients when it comes to addressing this issue well. We also know we need improvement in this area because even though most hospital settings that provide oncology care have financial counselors who have been tasked to deal with this problem, nonetheless, the problem remains. So it’s fair to ask, “What are we doing wrong?” and “How can we improve so that the financial toxicity we create for our patients is addressed at a level that truly meets the needs of our patients?” We would never accept using treatment models developed 20 years go to address the complexity of cancer care when new treatments are far superior to the old ones. Far too often, however, we accept this in the realm of financial advocacy for our patients.

So how do we address this better? I think we need to start looking at having the financial navigator trained and not just “learning on the job.” We also should look beyond the “20 years ago” solutions of Medicaid and charity care. It’s not that these solutions are wrong for some patients, but they do not solve the problem for a high percentage of our patients. The financial navigators should also be critical members of the multidisciplinary team. They need direct access to the oncologist, RNs, and social workers so that when the treatment plan is generated, the pending financial toxicity that will soon occur is addressed within the treatment plan.

Why has it become more difficult to identify those patients at risk for financial toxicity?

Dr. Zafar. Speaking as a researcher who has investigated this topic, it’s difficult to identify patients [at risk] because the traditional markers of socioeconomic disparity don’t apply when it comes to financial toxicity. It’s not like we can look at income, or zip code, or race

…if I’m prescribing a treatment for a patient, considering both the potential for physical and financial harms is well within my purview.

— Dr. Zafar
as markers to find patients who are at risk for receiving sub-par care as is traditionally done in health disparities research. The problem is that the patients who are at greatest risk are the patients who have poor quality insurance, and it’s very difficult to know who has poor quality insurance until they are hit with that catastrophic illness. That is the only time the patient really finds out they are under-insured. That is why it is difficult to identify patients who are at risk for financial toxicity unless you ask some very pointed questions about their insurance coverage.

From the provider perspective, why is it critical to identify patients at risk?

**Dr. Zafar.** When I make patient treatment decisions, I do so primarily on the immediate oncologic benefit to that patient. How is this going to help treat the patient’s cancer? But when cost to the patient is not a part of that consideration, and I don’t know how much that patient might pay out of pocket for that treatment, I could be causing that patient a great deal of financial harm. And I have done that and I’ve spoken previously about it. I know of specific patients where I’ve given them what I believe to be the best treatment for their cancer, but as a result they have incurred thousands of dollars of medical debt because I did not address their potential for financial toxicity.

Dan, from your perspective, why is it critical to identify the patients at risk?

**Dan.** It is essential to know which patients will most likely experience financial toxicity because early intervention is critical to resolving the issue. If we wait for the medical bill to arrive 60-90 days later, the solutions that were available early on will most likely no longer be an option. I believe the financial advocacy process should replicate the medical model. We provide anesthesia prior to surgery not after. Yet with financial advocacy, we typically intervene after treatment has been initiated. We wait, and the toxicity created can no longer be alleviated. Early identification of patients at risk for financial toxicity, allows us to proactively address the issue with the patient.

The model of financial advocacy that I use when meeting with patients is twofold: you address financial toxicity by (1) optimizing the patients’ health insurance coverage and (2) optimizing external assistance programs. For this model to be effective, it’s essential to address the pending toxicity prior to treatment. This accomplishes two things: first, it reduces the emotional distress of the patient and/or family and it does this as early on in the process as possible, and second, it reduces the out-of-pocket responsibilities for the patient. This results in a win for both the patient and provider. The patient receives the care they need with less financial distress and the provider is able to collect on the services provided.

To aid in early identification of patients at risk for financial toxicity, financial advocates must have a basic understanding of the clinical needs of patients. For example, I financially navigate a patient diagnosed with DCIS very differently than a patient with multiple myeloma. These patients have different needs on a different time table. Insurance optimization may be easier to accomplish with one diagnosis compared to the other. So incorporating the clinical needs of the patient plays a significant role in the early identification process. I often seek out patients with advanced stage disease as this type of diagnosis often results in financial distress. These patients also run the risk of losing their health insurance if they have coverage through a group policy from their employer. Early intervention in these cases is vital to protect them from the pending financial toxicity coming their way.

**Dr. Zafar.** Dan is definitely on the frontlines of intervening on this problem. As a provider, when I think about what it means to intervene on financial toxicity, again, I’m talking about patient engagement. While getting the patient to the financial counselor is where they will get the help oftentimes, as Dan mentioned earlier, the only person who can identify those patients is the physician who is about to prescribe the treatment. So in my mind, an intervention is as simple as asking a patient, “Do you have...
prescription drug coverage?” In fact that is how I could have avoided one of my patients facing thousands of dollars in out-of-pocket costs by asking that one simple question.

However, from a research perspective, we are developing some more detailed and multi-faceted interventions that promote patient engagement around the cost of care with their providers, which can help educate patients and help them find the resources that they need. In the meantime, I would advocate that tomorrow in clinic providers ask the question without being afraid that they don’t know what the answer is.

Unfortunately cancer services are still fragmented in some communities. How can the cancer care team best work together to address unwanted side effects of financial toxicity?

Dan. When you have a fragmented healthcare system, the task of providing care without causing financial distress becomes more difficult. I am blessed to work in a facility where all the services are provided under the same roof. This makes it more practical for one person to have the responsibility of communicating the financial navigation plan to all the providers. This is not the case in many community cancer programs. From my perspective it comes down to effective communication, providers being more aware of the problem and having all the different departments (Medical Oncology, Radiation Oncology, and Surgery) consider this problem to be a high priority to deal with. I would recommend that you have a screening process where you can identify the most likely patients who will experience financial toxicity. This information will then need to be communicated to the financial advocate who then can address problems as early as possible. Many of the financial navigation steps can be managed over the phone if necessary. The key again is early intervention. In facilities where fragmented care is occurring, the problem is often that the right person does not know that a problem exists. Focused attention on identifying the patient at risk for financial toxicity is therefore recommended in this type of setting. As one of the physicians in our cancer program recently stated, “Dan, we should treat every patient as if they do not have insurance. It makes us think through what we are doing to the patient.” If our providers started to think this way we would come a long way in decreasing financial distress for our patients.

Given the Commission on Cancer Standard mandating distress screening, would ensuring that financial issues were included in this screening help?

Dr. Zafar. I’m not sure distress screeners are as effective as we think they are. Many times, particularly in a busy clinic, they are not often reviewed the way they should be and it sort of falls into the mix of all the other symptoms that patient may be screened positive for. The problem in screening for financial toxicity, or any side effects for that matter, is how do you effectively capture and screen patients? And when do you do it? What is the right time to do it so that it impacts the treatment decision-making? I think it’s a step in the right direction to mandate symptom screening at our institution and we already include financial distress as part of that, but I don’t think we have good evidence as to how beneficial that is yet. That is part of what I’m working on is to see whether or not screening and identifying patients and prompting the physician, based on the patient’s screening results, is helpful.

How would you address concerns about disrupting or adding to the physician workflow and how providers and financial navigators can best work together?

Dr. Zafar. I want to be clear that this is just an example. It’s not going to fix the problem by any means, but it might help identify the issue for some and it is an example that resonates with a lot of providers. For example, in my clinic, if I’m going to prescribe a patient an oral anti-cancer drug, I will first stop by my pharmacist’s office before going into the patient’s room and let her know that this patient is going to get an expensive prescription. She will start looking up the patient’s
insurance to determine the patient’s co-pay amount. While she is doing this, I am talking to the patient about the benefits and physical risks of that drug. When I’m finished, the pharmacist will come in the room and tell the patient what the drug will cost and ask whether this is affordable. If not, I get pulled back for another discussion of treatment alternatives. The process is actually very efficient. One other point I’d like to make: There is some preliminary data from one of my colleagues at Duke who has found that a discussion about personal financial burden related to cancer treatment on average lasts about 1 to 2 minutes.

Dan, from your perspective, how does that communication work?

Dan. Dr. Zafar’s approach is pivotal, especially with oral oncolytics, which comprise around 30-35 percent of the oncology pipeline. We also need to be aware that on average 40-50 percent of your patient population will be in Medicare Part D. When you combine these new expensive oral cancer drugs (usually costing $8,000-$10,000 a month) and Medicare Part D, we know that the patient will most likely experience financial toxicity. A large number of these patients will end up refusing to fill their prescription when they discover that they face a co-pay of more than $2,000 the first time they try to fill it.

At our facility we have the medical oncologists contact the financial navigator when they prescribe high-dollar oral oncolytics. We then verify the benefits and attempt to fill the prescription while the patient is still at the facility. With this process we will know, while the patient is present, if we need to address a co-pay problem. Currently there are several foundations that provide instant approvals for co-pay assistance so the problem can often be solved before the patient leaves the cancer center. We also have a list of specific diagnoses for which high-dollar oncolytics are often prescribed, so that when a patient comes in with that specific diagnosis, we will often proactively analyze the problem while the oncologist is meeting with the patient. This process expedites the patient’s access to the medication, it improves communication between the provider and support staff, and it decreases financial distress for the patient.

Dr. Zafar’s solution is that before you walk into the room, you are starting to look at whether a financial barrier exists.

At our program, the financial navigator would be in close communication with the medical oncologist, and would try to address the co-pay issue while the patient was still here so that the patient leaves with a solution provided.

What are some of the factors fueling financial toxicity for patients with cancer?

Dr. Zafar. I think there are three factors that are contributing to higher costs. First, the drugs that we are prescribing are more expensive. Second, we’re using more of them and patients are on treatment for longer. Third, there is greater cost sharing. Together all of these factors are coming to a head at the same time.

In terms of cost sharing, deductibles have doubled, premiums have increased tremendously in the past decade, and particularly important for our patients, we are seeing a huge surge in the number of multi-tiered formularies. A recent Kaiser study that found that the number of multi-tiered formularies had increased to about a quarter of plans surveyed. This is particularly important for our patients because many of the expensive anti-cancer medications and some of the expensive supportive care medications that we prescribe fall into the higher tiers, resulting in more co-pays for our patients. So I think there is a shift toward patients bearing a greater cost burden.

And for some disease sites, patients have no choice but to reach for those higher cost, higher-shelf formulary drugs.

Dr. Zafar. Right. When we talk about cost sharing, this concept was first developed to reduce use of unnecessary...
patients have alternatives. For example, if patients are thinking about buying two separate medications—one for hypertension and one for hyperlipidemia—vs. buying a much more expensive combined pill. But for cancer patients that option does not exist. There is one drug and there is no alternative other than the option of not receiving treatment. For many patients that is not a palatable option.

Dan. To deal with financial toxicity we need to move away from the one-size-fits-all mentality. This mindset, unfortunately, is dominant in the medical financial advocacy discipline. We don’t treat every lung cancer patient in the same manner, as it depends on the type of stage of the cancer diagnosis. The treatments depend on the type and stage of the disease. However, with financial counseling, we often funnel patients through the same financial assessments and provide the same solutions to all the patients asking for help, which often ends in attempts to apply for Medicaid, charity, and co-pay assistance. This “one-size-fits-all” approach may help some patients, but we need to recognize that it does not work for all. If it did, financial distress would not be the number one concern of oncology patients. We need to start addressing the problem by customizing the patient’s financial navigation plan. We do this with all other aspects of their care but we don’t do it with something as important as their financial well-being.

Dr. Zafar. When I talk to oncologists about this topic, one of the first responses I often get is “I have no idea where to start. I don’t know what anything costs. How am I supposed to help my patients if I don’t have any answers?”

I think this is a reasonable concern. We don’t have a lot of answers. There is not a lot of price transparency in our healthcare system. But that shouldn’t prevent us from initially engaging our patients on this topic. We’ve got evidence to suggest that we’re already doing it. We are already decreasing some of the cost burden that patients are facing by engaging people like Dan and engaging our pharmacists early on in the process. Our studies talk to their doctors about cost, those costs are reduced without changing care.

What about the family’s involvement in this issue?

Dan. The family’s involvement plays an important role when it comes to customizing a financial navigation plan for the patient. We should acknowledge that the patient is overwhelmed with multiple issues on the day of consult. Adding in financial navigation services is critical, but at the same time, effective financial navigation services are often complex. It may be challenging for patients who are already overwhelmed to understand and absorb new terms and issues such as max out-of-pocket, co-insurance responsibilities, prior authorization requirements, and open enrollment guidelines. So I find it very helpful when family is present. Often family will play a significant role in helping me guide the patient to improved coverage for his or her treatments. There are also times when I will educate patients on how they can avoid large out-of-pocket responsibilities by purchasing health insurance policies that will provide improved coverage for their care. Patients can often do this when looking at ACA policies or Medicare plans. At times these policies come with a higher premium that the patient may not feel is affordable. When family is present and also informed, they may choose to assist their loved one with the increased cost of the premium. For all of these reasons, seeing the patient on the day of consult is beneficial, and family is usually present on this very important day.
Co-pay card programs are designed to make it easy for patients to use awarded funds and apply those funds to patient balances resulting from deductible or co-insurance amounts due that must be met before insurance pays 100 percent. To participate in a co-pay card program, patients apply (by phone, online, or via faxed applications) to the participating drug companies. The drug manufacturer presents patients with a co-pay assistance card and—once funds have been approved—the company provides an approval code so that patients can use the card to pay the funds into their account. Sounds easy, right? Not quite.

A colleague shared one anecdotal account of a patient who was given a co-pay assistance card and then used the funds to buy a refrigerator. While that may have indeed been a pressing need, if the goal is to use the program to help patients pay down their patient balances, I suggest that providers offer to “hold” co-pay cards and process payments for patients to help them avoid temptation to spend the money elsewhere.

Complexity of Applying Payments
Billing for infusion services is a complex process. St. Luke’s Mountain States Tumor Institute (MSTI) bills for infusion services on a recurring account once each month. On one hand, this process works well for patients who receive just one monthly bill for their infusion services. On the other hand, it makes the process of applying payments to specific infusion dates tricky. Additionally our billing and cash management office often takes payments and applies them to the oldest date of service owed—an automated function. When making specific payments, such as a payment from a co-pay card program, a manual process is needed to ensure the money is applied correctly.

Confusion for Hospital Billing & Payment Offices
Adding to the general confusion between the use of automated and manual billing processes, co-pay cards (which are often handed out to patients by physician offices) look very similar to credit cards or health savings account (HSA) cards (which also look like credit cards). When MSTI researched how to set up an effective co-pay card program, we discovered that some patients had tried doing this on their own and had used the co-pay cards to call up Customer Service to make payments. Unfortunately patients didn’t know to identify that they were using a co-pay card, and our Customer Service Department doesn’t identify the type of card used or the type of funds, so these payments were often assumed to be private payments or HSA funds.

To make the co-pay cards work for our patients, we saw a need for education and streamlined processes.
To make the co-pay cards work for our patients, we saw a need for education and streamlined processes.
Manpower Needed to Access Funds

In addition to the challenge of billing and cash management applying payments to access co-pay card funds, another difficulty we encountered was the manpower needed to actually submit claims to these companies to obtain the funds. Once a patient applied to the co-pay program, was approved, and then awarded funds, claims need to be submitted to obtain payment. To receive payment, the following items are needed:

- The actual itemization of charges that include the date of service, drug name, and CPT Code. In other words, a copy of the bill from the infusion center or hospital where the services were rendered.
- The patient’s Explanation of Benefits (EOB), showing that the claim was submitted to the patient’s insurance, how those charges were processed by the patient’s plan, and the out-of-pocket cost to the patient attributed by the insurance.

Getting patients to bring in the appropriate documentation can be challenging, especially at a time when they are often overwhelmed with the demands of treatment.

In 2013 I moved from the role of a patient financial advocate to my current role as manager of Revenue and Reimbursement for St. Luke’s MSTI. One of my goals in this new position was to figure out how to effectively manage the various co-pay card programs. My senior director is a great mentor who encouraged me to spend time thinking about how our co-pay process could be improved.

Identify the Need

My first step was to research all of the various co-pay programs our patients could possibly access. I looked at how many of our patients with commercial insurance had actually used the drugs covered by these programs in the past fiscal year, identifying about 1,110 patients. Then I asked a financial analyst to help calculate a “what if” scenario: What if these patients had not yet met their out-of-pocket needs, and what if those out-of-pocket costs averaged about $3,000 per patient.

Using this hypothetical scenario, I estimated what the savings would be if each of those 1,110 patients used a co-pay card. As we all know, payment collection for cancer patients is costly and can often result in bad debt write-offs or charity write-offs. By accessing the available co-pay programs, I estimated a conservative reduction in write-offs of $240,000—an amount that could be considered revenue back into the health system instead of going to write-offs.

Communicate the Benefits

Once I could show hospital leadership the patient need and the potential funds to be realized from use of co-pay cards, I had to find the manpower needed to actually obtain the funds. I looked to our Patient Financial Advocate team for help. Patient volumes were increasing, and so was the team’s workload. At the time, our patient financial advocates were responsible for:

- Financial screening
- Authorizations
- Federal, state, local, and hospital assistance applications
- Co-pay assistance
- Pharmacy assistance
- FMLA, Disability, and/or Cancer Claim Paperwork.

Looking at this workload, it was clear that adding co-pay assistance claims would overwhelm our already busy patient financial advocates, so I looked at what could be done to lighten the team’s load. My proposed solution: to hire a person to submit all patient claims to co-pay card programs and help the patient financial advocacy team with other tasks as needed. The next step was to obtain administrative approval for this new position.

At St. Luke’s MSTI, administration requires management to submit requests for staff or other needs using a Business Case or SBAR (Situation, Background, Assessment, and Recommendation). Thus far, I had the Situation and the Assessment, and now I needed to put the Recommendation together. I went to our Human Resource Department and found a current job description called...
authorization specialist that I felt might work for this new role I was developing. (This was advantageous as making a new job description requires a lot more time and effort than simply adopting a current job description to meet new needs.) The work that I was proposing for this staff role had little to no patient interaction and would mostly be completed in an office and/or clerical-type setting, so the authorization specialist job description appeared to be a good fit.

I proposed this staff role would have the following responsibilities in order of work priority:

- Co-pay assistance claims
- Drug replacement requests
- Cancer claim submissions
- Imaging authorizations.

Taking over drug replacement requests and cancer claim submissions for our patients and backing up the patient financial advocacy team during unexpected absences, holidays, and other staffing shortages would lighten the load for the entire team and also help to justify making it an FTE position, allowing our co-pay card program to grow. Bottom line: I justified adding one FTE with the potential annual gain of $240,000.

Discovery Along the Way
Administration approved my request, and I began recruiting my authorization specialist. At first I focused on the fact that the role was clerical and would not require extensive experience—just solid organizational skills to stay current with claims and to track them for payment. In January 2015, I hired a staff member from our billing office. She turned out to be a great fit, bringing to the table additional qualifications that helped her succeed in this new role. For example, our new authorization specialist had internal knowledge of MSTI’s billing software and therefore could pull claims and electronic remittance advices once those claims were processed to submit to the appropriate co-pay card program. Further, as a former insurance follow-up employee, she understood:

- CPT codes
- Contractual adjustments
- How to recognize when infusions had been billed to insurance or not; she could even reach out to the billing office when those claims needed to be rebilled.

These skills helped me understand that this role wasn’t simply a clerical role and that billing knowledge was a critical component to following up on our co-pay card claims.

Another discovery we made along our journey: our billing office had actually set up a generic insurance plan for external foundation assistance for organizations such as the Patient Access Network Foundation. As our new authorization specialist began to interact more and more with our billing and cash management offices, they started bringing these payments to her as they came in, and we helped improve these generic insurance plans so that funds were applied against the appropriate patient balances. As part of this process, we determined that the authorization specialist should also manage foundation assistance applications, so now our patient financial advocacy team sends those approved applications to her as well.

Outcome
MSTI is still tweaking the authorization specialist role and its co-pay program. Our patient financial advocacy team is working hard to ensure patients apply to the appropriate co-pay assistance programs and Foundations. (We’ve often said that adding a new process to our workload can take six months to a year to become routine.) My hope is that we have fine-tuned the process enough that we are ready for January 2016 when most patients start their new insurance plan year.

We have added a notification step in to our process to review all patients for financial assistance whenever patients receive New Treatment, Regimen Change, or Treatment Orders by their physician. The team looks up
the patients’ benefits at the time of the order, determines if they qualify for a co-pay card or foundation assistance, and notes their findings in the patients’ medical record. We’ve found that this extra process is a great opportunity to temperature check patient benefits. Recently, we implemented an incentive program wherein every quarter I send out a report from each clinic (we have five infusion clinics and three rural clinics), identifying the team that submitted for the most patient financial assistance that quarter. Interestingly, bagels and coffee have proven to be a great incentive and assistance is up!

As the authorization specialist and I have spread the word about our services and the co-pay assistance program, our healthcare system has met with us about replicating what we are doing at other service lines, such as Rheumatology. Developing the co-pay program has also improved our understanding of how we take payments from our patients and the importance of identifying where those payments are coming from and where funds are being applied. We may change the authorization specialist job description to medication specialist, which is better aligned to what this staff member is doing.

**Future Plans**

Our current co-pay card process is manual, and we would like to see that improved. The authorization specialist faxes all claims and retains fax confirmation as proof of claim submission. The process is not ideal; for example, one drug manufacturer randomly sends a return fax stating the claim was received but with no patient identifiers. (A second fax often comes a day or so later.)

We would like drug manufacturers to set up online processes so that we could upload claims and documentation in a real-time environment. Web-based co-pay programs would allow us to see the claims submitted, where those claims are in processing, when payment will be submitted, and the amount of funds each patient has left. Currently the only way to get this information is for the authorization specialist to call and ask the appropriate co-pay assistance program. One interesting finding: many individuals at these co-pay assistance programs have little to no billing knowledge, making it challenging to have robust discussion.

In short, St Luke’s MSTI has developed an effective process for applying for co-pay assistance and ensuring that staff are appropriately applying funds to the appropriate accounts, and now we are waiting for pharmaceutical manufacturers to speed up their payment processes. We have a large amount of co-pay funds awaiting payment, and they are slow in coming into our cancer program. I am working to engage the various drug manufacturers in conversation to see how we can encourage them to set up online support systems to access payments faster.

Would I do this again? You bet! Our patient financial advocacy team has received strong support from the new authorization specialist position—as has our patients who truly appreciate the additional help with their out of pocket costs. The cost of adding this new FTE position to our team is already being recouped in pending payments, so the program is a win for all. More to come as we continue to refine this position and program.

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Ann Kaley Kline is manager, Revenue & Reimbursement at St. Luke’s Mountain States Tumor Institute, Boise, Idaho.
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TECHNICAL ADVISORY COUNCIL
**STEP 1.** Provider writes chemotherapy order for patient.

**STEP 3.** Staff identifies the patient’s financial status and follows the appropriate flow chart below.

<table>
<thead>
<tr>
<th>No Insurance</th>
<th>Identify if patient qualifies for any programs (SSDI, Medicaid, etc.). Identify if replacement drugs are available.</th>
<th>Fill out forms for all programs. Complete forms for companies that have a replacement program if patient qualifies.</th>
<th>Identify if foundation funding is available for any drugs not replaced.</th>
<th>Fill out forms for foundation funding that is available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid Program</td>
<td>Verify benefits.</td>
<td>Verify drugs are indicated for diagnosis and authorize if necessary.</td>
<td>Identify if replacement drugs are available if necessary; will need to appeal to receive drugs.</td>
<td>Identify patient’s responsibility.</td>
</tr>
<tr>
<td>Medicare Only</td>
<td>Verify benefits.</td>
<td>Verify drugs are indicated for diagnosis.</td>
<td>Identify if replacement drugs are available if necessary; will need to appeal to receive drugs.</td>
<td>Identify patient’s responsibility.</td>
</tr>
<tr>
<td>Medicare &amp; Supplemental</td>
<td>Verify benefits.</td>
<td>Verify drugs are indicated for diagnosis.</td>
<td>Identify if replacement drugs are available if necessary; will need to appeal to receive drugs.</td>
<td>Identify patient’s responsibility; if none, start treatment.</td>
</tr>
<tr>
<td>Medicare &amp; Secondary</td>
<td>Verify benefits.</td>
<td>Verify drugs are indicated for diagnosis and authorize secondary insurance if necessary.</td>
<td>Identify if replacement drugs are available if necessary; will need to appeal to receive drugs.</td>
<td>Identify patient’s responsibility.</td>
</tr>
<tr>
<td>Medicare Advantage</td>
<td>Verify benefits.</td>
<td>Verify drugs are indicated for diagnosis and authorize secondary insurance if necessary.</td>
<td>Identify if replacement drugs are available if necessary; will need to appeal to receive drugs.</td>
<td>Identify patient’s responsibility.</td>
</tr>
<tr>
<td>Other Government Programs</td>
<td>Verify benefits.</td>
<td>Verify drugs are indicated for diagnosis and authorize secondary insurance if necessary.</td>
<td>Identify if replacement drugs are available if necessary; will need to appeal to receive drugs.</td>
<td>Identify patient’s responsibility.</td>
</tr>
<tr>
<td>Managed Care</td>
<td>Verify benefits.</td>
<td>Verify drugs are indicated for diagnosis and authorize secondary insurance if necessary.</td>
<td>Identify if replacement drugs are available if necessary; will need to appeal to receive drugs.</td>
<td>Identify patient’s responsibility.</td>
</tr>
<tr>
<td>Commercial &amp; Insurance Exchanges</td>
<td>Verify benefits.</td>
<td>Verify drugs are indicated for diagnosis and authorize secondary insurance if necessary.</td>
<td>Identify if replacement drugs are available if necessary; will need to appeal to receive drugs.</td>
<td>Identify patient’s responsibility.</td>
</tr>
</tbody>
</table>
### STEP 2. Chemotherapy order is sent to finance staff.

<table>
<thead>
<tr>
<th>Action</th>
<th>Scenario</th>
<th>Action</th>
<th>Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify if patient qualifies for charity care within the clinic or institution and complete paperwork.</td>
<td>Create payment plan for any balance (if available) or collect balance.</td>
<td>Create payment plan for any balance (if available) or collect balance.</td>
<td></td>
</tr>
<tr>
<td>Collect out-of-pocket costs.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identify if foundation assistance is available.</td>
<td>Fill out forms for foundation funding that is available.</td>
<td>Identify if patient qualifies for charity care within the clinic or institution and complete paperwork.</td>
<td>Create payment plan for any balance (if available) or collect balance.</td>
</tr>
<tr>
<td>Identify if foundation assistance is available.</td>
<td>Fill out forms for foundation funding that is available.</td>
<td>Identify if patient qualifies, send in EOB and/or anything else to help verify amount for foundation to pay.</td>
<td>If any balance, create payment plan for any balance (if available) or collect balance.</td>
</tr>
<tr>
<td>Identify if foundation assistance is available.</td>
<td>Fill out forms for foundation funding that is available.</td>
<td>Identify if patient qualifies, send in EOB and/or anything else to help verify amount for foundation to pay.</td>
<td>If any balance, create payment plan for any balance (if available) or collect balance.</td>
</tr>
<tr>
<td>Identify if foundation assistance is available.</td>
<td>Fill out forms for foundation funding that is available.</td>
<td>Identify if patient qualifies, send in EOB and/or anything else to help verify amount for foundation to pay.</td>
<td>If any balance, create payment plan for any balance (if available) or collect balance.</td>
</tr>
<tr>
<td>Identify if foundation assistance is available.</td>
<td>Fill out forms for foundation funding that is available.</td>
<td>Identify if patient qualifies, send in EOB and/or anything else to help verify amount for foundation to pay.</td>
<td>If any balance, create payment plan for any balance (if available) or collect balance.</td>
</tr>
<tr>
<td>Identify if manufacturer assistance is available and fill out forms if applicable.</td>
<td>If no manufacturer assistance, then identify if foundation assistance is available.</td>
<td>Fill out forms for foundation funding that is available.</td>
<td>If patient qualifies for manufacturer or foundation assistance, send in EOB and/or anything else to help verify amount owed.</td>
</tr>
<tr>
<td>If no manufacturer assistance, then identify if foundation assistance is available.</td>
<td>Fill out forms for foundation funding that is available.</td>
<td>If patient qualifies for manufacturer or foundation assistance, send in EOB and/or anything else to help verify amount owed.</td>
<td>Process payment using co-pay card or whatever form of payment the program has.</td>
</tr>
<tr>
<td>If no manufacturer assistance, then identify if foundation assistance is available.</td>
<td>Fill out forms for foundation funding that is available.</td>
<td>If patient qualifies for manufacturer or foundation assistance, send in EOB and/or anything else to help verify amount owed.</td>
<td>Process payment using co-pay card or whatever form of payment the program has.</td>
</tr>
<tr>
<td>If any balance, create payment plan (if available) or collect balance from patient.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identify if manufacturer assistance is available and fill out forms if applicable.</td>
<td>If no manufacturer assistance, then identify if foundation assistance is available.</td>
<td>Fill out forms for foundation funding that is available.</td>
<td>If patient qualifies for manufacturer or foundation assistance, send in EOB and/or anything else to help verify amount owed.</td>
</tr>
<tr>
<td>If any balance, create payment plan (if available) or collect balance from patient.</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>DRUG NAME</td>
<td>BRAND NAME</td>
<td>DRUG COMPANY</td>
<td>BENEFIT VERIFICATION AND AUTHORIZATION SUPPORT</td>
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<tr>
<td>-------------------------------</td>
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<tr>
<td>13-cis-Retinoic Acid</td>
<td>Acutane</td>
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<td>2-GDA</td>
<td>Leustatin</td>
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<td>2-Chlorodeoxyadenosine</td>
<td>Leustatin</td>
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<td>3-Azacytidine</td>
<td>Vidaza</td>
<td>Celgene</td>
<td>X</td>
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<tr>
<td>5FU</td>
<td>Adriocil</td>
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<td>6-Mercaptopurine</td>
<td>Purinethol</td>
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<td>6-MP</td>
<td>Purinethol</td>
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<tr>
<td>6-TG</td>
<td>Thioguanine Tab</td>
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<tr>
<td>6-Thioguanine</td>
<td>Thioguanine Tab</td>
<td>X</td>
<td></td>
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<td>Abiraterone acetate</td>
<td>Zytiga</td>
<td>Janssen Biotech</td>
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<td>Ado-trastuzumab emtansine</td>
<td>Kadcyla</td>
<td>Genentech</td>
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<td>Aflatinib</td>
<td>Gilotrif Tablets</td>
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<td>Aegrin</td>
<td>Shire</td>
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<td>Anastrozole</td>
<td>Arimidex</td>
<td>AstraZeneica</td>
<td>A</td>
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<tr>
<td>Aprepitant</td>
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Oncology-related products: Lupron Depot® (leuprolide acetate for depot suspension)

**PATIENT ASSISTANCE**

**AbbVie Patient Assistance Foundation**
The foundation offers a variety of assistance programs to meet the needs of the specific people who are prescribed AbbVie medications. Income eligibility criteria varies by medication and is based on the federal poverty guidelines, which are adjusted each year. To apply:
- Click on the medication (abbviepaf.org/apply.cfm).
- Complete the application. Fill out the sections completely (please refer to the checklist on the application).
- Attach proof of income if required.
- Be sure the patient and provider sign and date the application.
- If patient has Medicare Part D and is applying for assistance, download and complete the appropriate attestation form.

Submit the completed application by fax: 866.483.1305 or mail: AbbVie Patient Assistance Foundation, PO Box 270, Somerville, NJ 08876. Questions? Call 1.800.222.6885, Monday through Friday, 8:00 am to 5:00 pm CST.

The foundation will contact patients and providers about the application within a week to let patients know if they are approved for assistance. If the application was missing information the patient and/or provider will be asked to provide missing information. Once received, the foundation will evaluate the application. The foundation will contact patients and providers about the application to let them know if the patient is now approved for assistance.

If the patient is eligible for assistance, a supply of the medication will be shipped to the prescriber’s office. It is the responsibility of the prescriber or office staff to reorder at least 7 business days prior to the patient requiring further medication.

**REIMBURSEMENT ASSISTANCE**

**Reimbursement Resources**
Providers with reimbursement questions can call the toll-free reimbursement hotline at: 1.800.453.8438. If you are experiencing reimbursement issues, customer service representatives are available to assist.
Patient and Reimbursement Assistance Website
onyx360.com

PATIENT ASSISTANCE

Co-pay Assistance Support
Amgen offers co-pay coupon programs for Imlygic, Kyprolis, Neulasta, Neupogen, Nplate, Prolia, Vectibix, and Xgeva to help eligible patients who are commercially insured with their deductible, co-insurance, and/or co-payment requirements. To confirm patient eligibility and enroll in one of these programs, call 1.888.65.STEP1 (888.657.8371) or visit amgenfirststep.com.

Amgen FIRST STEP™ Program
This financial support program helps commercially-insured eligible patients with their co-pay and other treatment costs. Patient eligibility requirements:

- Patients must be prescribed one of the drugs listed above.
- Patients must have private commercial health insurance that covers medication costs for the drugs listed above. Patients must not participate in any federal, state, or government-funded healthcare program, such as Medicare, Medicare Advantage, Medicaid, MediGap, VA, DoD, or TriCare.
- Patients may not seek reimbursement for value received from the Amgen FIRST STEP Program from any third-party payers, including flexible spending accounts or healthcare savings accounts.

Coverage Limits

- Program covers out-of-pocket medication costs for the Amgen product only. Program does not cover any other costs related to office visit or administration of the Amgen product. Other restrictions may apply.
- No out-of-pocket cost for first dose or cycle; $25 out-of-pocket cost for subsequent dose or cycle. Maximum benefit of $10,000 per patient per calendar year. (For Prolia: maximum benefit of $3,000 per patient per calendar year. For Kyprolis: maximum benefit of $20,000 per patient per calendar year.) Patient is responsible for costs above these amounts.

Restrictions may apply. Amgen reserves the right to revise or terminate this program, in whole or in part, without notice at any time. This is not health insurance. Program invalid where otherwise prohibited by law. Register before any Amgen treatment.

Learn more at the Amgen FIRST STEP Co-pay Card Program Health Care Provider Portal: amgenfirst-step.com/hcp. From the portal, healthcare providers can enroll patients, review records, download forms, and upload documents. Questions? Call 1.888.65.STEP1 (1.888.657.8371) Monday through Friday, 9:00 am to 8:00 pm EST.
Uninsured Patients

Patients may be able to receive Amgen medications at no cost from The Safety Net Foundation (safetynetfoundation.com/index.html) if they meet the following eligibility requirements:

- Are a resident of the U.S. or its territories
- Satisfy income eligibility requirements
- Have no or limited drug coverage
- Do not have any other insurance or financial support options

NOTE: Qualifying Medicare Part D patients may also be eligible if they meet additional criteria demonstrating inability to afford medications based on income.

To enroll in The Safety Net Foundation, patients must meet program eligibility requirements and complete the Patient Application Form:

- (English) http://www.safetynetfoundation.com/pdf/ Application_V12_Patient_Administered_English_ June_2016.pdf
- (Spanish) http://www.safetynetfoundation.com/pdf/ Application_V12_Patient_Administered_Spanish_ June_2016.pdf

Please note: As of June 2016 all applications have been updated. Beginning October 1, 2016, outdated versions of this application will no longer be accepted. To get started, complete the Patient Application Form above. For prescription products, physicians must complete the Product Prescription Form (safetynetfoundation.com/pdf/RE-SNF-007-A-ProductPrescriptionForm_V1.pdf) or submit an original prescription. For replacement products, the facility must first enroll in The Safety Net Foundation (safetynetfoundation.com/pdf/RE-SNF-002-P_V2_Facility_Application.pdf). The facility can then submit requests for replacement product using the Product Replacement Request Form (http://www.safetynetfoundation.com/pdf/Product_Replacement_Form_3_28_16.pdf). Institutions that have enrolled as Individual Patient Assistance Program (IPAP) facilities may use the IPAP Patient Application (safetynetfoundation.com/pdf/RE-SNF-011-C_IPAP_Patient_Application_UpdatedV3.pdf) to enroll their patients.

Questions? Call 1.888.762.6436.

Amgen Assist 360™

This comprehensive, personalized program provides information and patient assistance for patients on Blincyto and Kyprolis, including:

- Insurance Verification
  Verifying patient’s insurance information and determining patient coverage responsibility for services to be provided
- Free product assistance for uninsured patients or those rendered uninsured through payer denial who meet certain income, medical, and eligibility criteria
- Independent foundation assistance. Co-pay and/or co-insurance assistance through third-party foundations
- Appeals Support
  Appeals process information
- Transportation and lodging
  cost assistance. Referral to third-party organizations for those patients who qualify and need assistance with or help paying for gas, lodging, tolls, and parking in connection with receiving therapy
- Patient and caregiver support services. Referral to support services for patients, families, and caregivers that provide product information, support group information, nutritional information, side effect management, along with practical matters related to the patient’s condition

Providers can enroll their patients online at: http://www.amgenassist360.com/hcp/. All services are subject to eligibility requirements. The online form includes three sections, and you should have the following information available:

Section 1. Patient Information
1. Your patient’s contact information, including address and phone number
2. Your professional contact information

Section 2. Physician Information
1. Your professional contact information
2. The referring physician’s contact information
3. Your state license, DEA number, tax ID number, NPI/PTAN number, patient diagnosis ICD-9 code, patient dose, treatment
start date, and previous patient therapy information

Section 3. Insurance Information
1. Your patient’s insurance information, including carrier, phone number, policy ID, group number, and subscriber’s date of birth

Section 4. Free Product Assistance
1. Your patient’s current annual household adjusted gross income
2. Your patient’s federal tax return, W2 form, or Social Security benefit statement

You can also enroll patients by phone by calling 1.888.4ASSIST (1.888.427.7478) Monday through Friday, 9:00 am to 8:00 pm EST.

REIMBURSEMENT ASSISTANCE

Amgen Assist 360™
This comprehensive, personalized program provides information and reimbursement assistance for patients on Blincyto and Kyprolis, including:

• Insurance verification. Verifying patient’s insurance information and determining patient coverage responsibility for services to be provided.
• Appeals support.

Providers can enroll their patients online at: http://www.amgenassist360.com/hcp/ (see the instructions above) or by calling: 1.888.4ASSIST (1.888.427.7478) Monday through Friday, 9:00 am to 8:00 pm EST.
PATIENT ASSISTANCE

ARIAD PASS™
To support your patients, ARIAD has partnered with Biologics, an oncology pharmacy that provides a comprehensive and personalized approach to supporting patients throughout their prescribed therapy. Each of your ARIAD patients will be assigned a Biologics Oncology Pharmacist and Nurse Specialist to provide clinical support from receipt of prescription throughout treatment.

Enrolling your patients in ARIAD PASS is easy with the ARIAD PASS Prescription Form found online at: ariadpass.com/hcp.html, which can be faxed to ARIAD PASS at 1.855.557.PASS (1.855.557.7277).

A Patient Access Specialist will conduct a benefits investigation and provide the results. The patient access specialist will also work with patients who are unable to identify programs or services for which they may be eligible. Once a benefits investigation is complete, a Biologics Oncology Pharmacist will contact your patient to schedule delivery and perform an initial baseline assessment. The Biologics multidisciplinary pharmacy care team will:

- Counsel your patient, including a review of drug and food interactions, dosage, and possible side effects
- Provide information on adherence and side effect management support throughout therapy
- Coordinate with your patient to set up free delivery and free refill delivery based on your patient’s therapy schedule
- Contact your office if a new prescription is needed
- Advise your patients on how to take, store, and properly dispose of medication.

The Patient Access Specialist provides eligible patients with an array of financial assistance options, including co-pay or co-insurance support, based on their insurance coverage and financial needs. If your patient requires medication during a coverage delay, the benefits coordinator can provide your patient with a one-time, 30-day supply to ensure that they can start medication free of cost. If your patient has a qualifying disruption in insurance coverage ARIAD has created ARIAD Assurance PASS. The plan is designed to ensure that patients who start on treatment are able to stay on treatment even if there’s a change in their insurance status. For ARIAD Assurance PASS, medication can be provided at no cost for up to 90 days. There are three ways you can get your patients access to ARIAD PASS:

1. Call toll-free 1.855.447.PASS (1.855.447.7277) Monday through Friday, 9:00 am to 6:00 pm EST
2. Visit ariadpass.com to download the Prescription Form, then fax the completed ARIAD PASS Prescription Form to 1.855.557.PASS (1.855.557.7277)

REIMBURSEMENT ASSISTANCE

ARIAD PASS
A Patient Access Specialist quickly determines your patient’s level of insurance coverage and any additional requirements, such as prior authorizations, so your patient can promptly begin therapy.
**PATIENT ASSISTANCE**

**Xtandi Support Solutions℠**

Xtandi Support Solutions (astellaspharmasupportsolutions.com/products/xtandi) provides services to help patients and healthcare providers with access and reimbursement, and information regarding coverage options and financial assistance programs.

Xtandi Support Solutions offers:

- Instructions for filling out the Xtandi Solutions patient enrollment form
- Benefits verification
- Prior authorization requests
- Assistance with appeals when prior authorization requests are denied
- Xtandi Quick Start+ Program
- Patient assistance
- Specialty pharmacy coordination.

To enroll your patient in Xtandi Support Solutions, complete the Patient Enrollment Form (astellaspharmasupportsolutions.com/docs/xtandi/XSS_Patient_Enrollment_Form.pdf) in its entirety (required fields marked with an asterisk), including the signatures section. (NOTE: It is critical that the enrollment form is signed by both the prescribing doctor and the patient or the patient’s authorized representative.)

Return by fax to 1.855.982.6341.

**Xtandi Quick Start+™ Program**

The Xtandi Quick Start+ Program provides a free, one-time 14-day supply of Xtandi to new patients who experience a delay in insurance coverage. Providers should complete the Quick Start+ Program portion of the Patient Enrollment Form so their patients will be eligible for the program if needed. If prescriptions are not filled within 7 business days due to insurance coverage delays, Xtandi Support Solutions assesses the case for eligibility. A 14-day supply of Xtandi is shipped overnight directly to the patient.

In order to be eligible for the Quick Start+ program, patients need to:

- Be new to Xtandi therapy
- Have experienced an insurance-related access delay
- Have been prescribed Xtandi for an FDA-approved indication.

Xtandi Quick Start+ Program allows your patient to start their Xtandi treatment while Xtandi Support Solutions or a network specialty pharmacy works with the patient’s insurer to resolve coverage issues.

**Commerci ally Insured Patients**

The Xtandi Patient Savings Program is for patients who have commercial and/or private health insurance but who may have trouble paying their out-of-pocket costs. Under this program:

- Patients should expect to pay no more than $20 per prescription
- Co-pay assistance is available for up to 12 refills
- Your patient is covered for savings up to $5,000 for each prescription and a maximum savings up to $25,000 per year
- There are no income requirements.
The program is not available to patients who have prescription drug coverage paid in part or in full under any state or federally funded programs, including but not limited to Medicaid, Medicare, Medicare Part D, Medigap, DoD, VA, TRICARE, or any state patient or pharmaceutical assistance program.

To enroll your patient in Xtandi Patient Savings Program, complete the Xtandi Support Solutions Patient Enrollment Form (astellaspharmasupportsolutions.com/docs/xtandi/XSS_Patient_Enrollment_Form.pdf), including all patient and healthcare provider signatures, and fax the completed form to 1.855.982.6341 or contact your preferred network specialty pharmacy to determine eligibility and enroll in the program.

Uninsured Patients
The Astellas Access Program is for patients without prescription coverage for Xtandi. The Program provides free Xtandi to patients who qualify. Eligibility is determined on a patient-specific basis. To be eligible for the Astellas Access Program patients must meet the following criteria:

- Patient is uninsured or has insurance that has denied coverage for Xtandi
- Patient has a verifiable shipping address in the United States
- Patient has been prescribed Xtandi for an FDA approved indication
- Patient has an annual adjusted gross household income of less than $100,000 per year

Xtandi Support Solutions can determine whether a patient meets these criteria. To enroll a patient with the Astellas Access Program, complete the Xtandi Support Solutions Patient Enrollment Form (including the signatures section of this form) (astellaspharmasupportsolutions.com/docs/xtandi/XSS_Patient_Enrollment_Form.pdf) and fax it to 1.855.982.6341. Retain a copy of your patient’s proof of income, which may include one of the following:

- Copy of the patient’s most recent tax return
- Copy of the patient’s most recent W-2 form
- Copy of the patient’s 1099 Social Security form
- Copy of the patient’s most recent Social Security benefits letter
- Copy of the patient’s latest pay stubs for 4 consecutive pay periods.

Once your patient is approved for assistance under the Astellas Access Program, Xtandi Support Solutions will notify both the prescriber and patient. A 30-day supply of Xtandi is then shipped directly to the patient’s home each month they are enrolled in the program.

Medicare Patients
Medicare typically covers Xtandi under the Medicare Part D prescription drug benefit. However, a patient’s cost share may vary, depending on their Medicare plan. Xtandi Support Solutions can help evaluate a Medicare patient’s financial need and assistance options. Xtandi Support Solutions can:

- Help determine what type of cost-sharing the patient has, such as a flat co-payment or a percentage-based co-insurance
- Evaluate eligibility for Medicare Part D patients who may qualify for the Low-Income Subsidy (LIS)
- Help determine whether a patient is eligible for assistance from an independent co-pay foundation

REIMBURSEMENT ASSISTANCE

Xtandi Support Solutions
Specialists are available to help patients find the best option to gain rapid access to Xtandi. Xtandi Support Solutions can help with:

- Reimbursement support (benefit verification, prior authorization tracking, appeal assistance)
- Prescription triage to a specialty pharmacy in the Xtandi Support Solutions network
- Questions on using specialty pharmacies
- Support for in-office dispensers
- Referrals to programs to help with out-of-pocket expenses
- Facilitating immediate access to Xtandi via the Quick Start+ program
- Determining patient eligibility for the Astellas Access Program.
Benefits Verification
Xtandi Support Solutions performs the benefits verification upon receipt of the Patient Enrollment Form. After performing a comprehensive assessment of patient coverage for Xtandi, Xtandi Support Solutions provides patients with a summary of benefits that includes:
• The patient’s insurance coverage requirements for Xtandi
• Requirements for prior authorization, step edit, or other coverage restrictions
• Cost-sharing responsibility, including deductibles, co-insurance or co-payment, and out-of-pocket maximums
• A list of specialty pharmacies that participate in your patient’s insurance coverage.

Xtandi Support Solutions will send your office a summary of benefits typically within 2 hours of receipt of the Patient Enrollment Form.

Prior Authorization
Xtandi Support Solutions will determine whether a patient’s plan requires prior authorization for Xtandi, and if it does, how to obtain the prior authorization. Xtandi Support Solutions will also:
• Provide a summary of prior authorization requirements and obtain the appropriate prior authorization form
• Pre-populate the prior authorization form using the information provided on the patient enrollment form
• Send the form to the healthcare provider to complete and sign
• If the healthcare provider returns the completed form to Xtandi Support Solutions, Xtandi Support Solutions will submit the completed form to the patient’s insurer.

At the request of the healthcare provider, Xtandi Support Solutions will follow up with the patient’s insurer to confirm receipt of the prior authorization form, check on the status of the form, and determine the outcome. Xtandi Support Solutions will follow up with the healthcare provider regarding the prior authorization results, inform them if any additional information is required, and assist with denial appeals as necessary.

Prior Authorization Denial Appeals
If a patient’s insurer denies a claim or prior authorization request, Xtandi Support Solutions can assist with the appeals process by:
• Identifying the reason for the denied claim or prior authorization request
• Determining the additional required documentation
• Informing the healthcare provider what information is needed and where to send the appeal
• Tracking and relaying the status of the appeal.

Astellas Access eService Portal
The Astellas Access eService tool is an interactive website for healthcare providers to securely and efficiently submit, track, and manage requests online. Available 24 hours a day, eService allows providers to:
• Submit, track, and view the results of benefit verifications
• Submit, track, and view the results of Astellas Access Program applications.

Go to https://eservice.astellasaccess.com/ to get started with Astellas Access eService.
Oncology-related Products: Arimidex® (anastrozole), Caprelsa® (vandetanib), Casodex (bicalutamide), Faslodex® (fulvestrant), Iressa (gefitinib), Lynparza® (olaparib), Tagrisso™ (osimertinib) tablets, Zoladex® (goserelin acetate)

PATIENT ASSISTANCE

AZ&Me™ Prescription Savings Program
If patients take certain AstraZeneca medicines and cannot afford them, they may qualify for the AZ&Me Prescription Savings Program. To determine which AZ&Me Prescription Savings Program patients may be eligible for call: 1.800.AZandMe (1.800.292.6363) or go online to: azandmeapp.com. Have the following information available before beginning the pre-screening process:
• The name(s) of the AstraZeneca medication(s) the patient is prescribed
• Information about whether the patient has prescription drug coverage
• Information about the patient’s total household income.

Patients Without Insurance
The AZ&Me Prescription Savings Program can provide AstraZeneca medicines at no cost to qualified patients. This patient prescription assistance program can help patients who do not have prescription drug coverage and who meet the eligibility criteria listed below. Highlights of the program include:
• AstraZeneca medicines provided at no cost.
• There is no cost to sign up for the program.
• Once accepted, patients remain enrolled for up to one year. At the end of that year, patients can reapply.
• Drugs are mailed to the provider or the patient’s home.
• The provider, patient, or caregiver can request refills.
• Providers can review the list of medicines available through this program at: azanmeapp.com/eligibility.

To enroll your patient in the AZ&Me Prescription Savings Program by mail, download and complete the application form (azandmeapp.com/assets/app.pdf) and mail to: AZ&Me Prescription Savings Program, PO Box 898, Somerville, NJ 08876. Or fax the completed form to 1.800.961.8323.

NOTE: Faxed applications must be sent from the doctor’s office in order for their prescription to be processed. Or enroll by phone by calling 1.800.AZandMe (292.6363).

Eligibility requirements. Patient is a U.S. citizen or has a Work Visa or Green Card. Patients are not currently receiving prescription drug coverage under a private insurance or government program, or receiving any other assistance to help pay for medicine. Patients have an annual income that is at or below:
• $35,000 for a single person
• $48,000 for a family of two
• $60,000 for a family of three
• $70,000 for a family of four
• $80,000 for a family of five.

NOTE: Income eligibility criteria for some specialty and/or oncology products may be different from the income levels listed above. Call 1.800.AZandMe (1.800.292.6363) for more information or visit: azandmeapp.com/requirements. Apply by following the instructions discussed above.
Patients with Medicare Part D Insurance
The AZ&Me Prescription Savings program provides AstraZeneca medicines at no cost to qualified patients enrolled in a Medicare Part D prescription drug coverage plan who are having difficulty affording their AstraZeneca medicine(s). Highlights of the program include:
- AstraZeneca medicines provided at no cost.
- There is no cost to sign up for this program.
- Once enrolled, patients remain enrolled for up to one year. Patients may reapply at the end of that year.
- Drugs are mailed to the provider or the patient’s home.
- The provider, patient, or caregiver can request refills by calling 1.800.292.6363.

To be eligible for assistance, Medicare Part D beneficiaries must not be eligible for or enrolled in Limited Income Subsidy (LIS) for Medicare Part D, and meet the annual income limits above. Apply by following the instructions discussed above.

Patients Experiencing Financial Hardship
If patients have experienced a life changing event in the past year, and their financial documentation does not accurately reflect their current situation, they should apply for the AZ&Me Prescription Savings Program, as they may still meet the criteria to enroll. Some examples of this type of event would be:
- Loss of employment
- Change in income
- Loss of, or change in, prescription drug coverage
- Marriage
- Change in household number.

Healthcare Facilities
The AZ&Me Prescription Savings Program helps provide AstraZeneca medicines to low-income patients through qualifying facilities such as:
- Disproportionate share hospitals
- Community health centers
- Community free clinics
- Central fill pharmacies
- Charitable pharmacies.

Highlights of the program include:
- Bulk replacement program based on a facility’s qualifying product utilization.
- Facilities can receive and dispense AstraZeneca medicines at no cost or for a nominal, facility-assessed dispensing fee from their outpatient pharmacy or dispensary to qualified patients.
- Facilities remain enrolled for two years and then may re-enroll.
- Prescriptions are provided to patients at the point of care.

Facility qualification criteria includes, but is not limited to:
- Existence of an on-site, licensed outpatient pharmacy or dispensary
- Tax-exempt status
- Robust policies and procedures
- Facility patient eligibility criteria that is consistent with AstraZeneca Program guidelines for patient eligibility, including patient income thresholds, lack of patient prescription insurance, and annual patient eligibility review.

REIMBURSEMENT ASSISTANCE
Access 360™
This comprehensive affordability and reimbursement program provides a range of support options, including:
- Dedicated Access 360 Specialists who can develop an in-depth benefits investigation report
- Identification of distribution options and pharmacy coordination for submissions and shipments
- Prior authorization research and follow up with the insurance company until a decision is obtained
- Appeals support in the event of a denial
- Assistance determining which affordability programs are appropriate for patients and directions on how to apply.
Oncology-related product: Nexavar® (sorafenib) tablets, Stivarga® (regorafenib) tablets, Xofigo® (radium Ra 223 dichloride injection)

Bayer HealthCare Pharmaceuticals, Inc.

PATIENT ASSISTANCE

Xofigo Access Services

Uninsured Patients

You must apply for assistance on your patient’s behalf by submitting a completed application (hcp.xofigo-us.com/downloads/PP-600-US-1278_Xofigo_Access%20Services%20PAP_Copay%20App_Digital.pdf), including a signed patient authorization. Eligibility criteria include:

- Financial criteria based on adjusted gross household income (documentation of income is required)
- Residency in the United States, including the District of Columbia, Puerto Rico, Guam, or the U.S. Virgin Islands
- Treatment provided in an outpatient setting.

Call an Access Counselor at 855.6XOFIGO (1.855.696.3446), 9:00 am to 8:00 pm EST, Monday through Friday, if you have any questions or to obtain more information. Fax a completed application, including the signed patient authorization to 1.855.963.4463. Registered users can also submit an application for patient assistance via the secure Xofigo Access Services Provider Portal: xofigoaccessonline.com.

Co-Pay Assistance for Patients with Private Commercial Insurance

You must apply for assistance on your patient’s behalf by submitting a completed application, including a signed patient authorization. Eligibility criteria include:

- Financial criteria based on adjusted gross household income (documentation of income is required)
- Residency in the United States, including the District of Columbia, Puerto Rico, Guam, or the U.S. Virgin Islands
- Treatment provided in an outpatient setting.

You and your patient must sign and submit the Application for Patient Assistance/Commercial Co-pay Assistance that includes a signed patient authorization. By signing this form, the patient gives permission for the program to pay co-pay/co-insurance assistance funds directly to the provider. Once approved, your patient receives an approval letter with a Commercial Co-pay/Co-insurance Assistance identification (ID) card. Patients approved for assistance will not have to pay anything to access Xofigo. Call an Access Counselor at 1.855.6XOFIGO (1.855.696.3446), 9:00 am to 8:00 pm EST, Monday through Friday, if you have any questions or to obtain more information. Registered users can also submit an application for patient assistance via the secure Xofigo Access Services Provider Portal: xofigoaccessonline.com.

Co-Pay Assistance for Patients Insured by Public Payers

Medicare beneficiaries and patients with other government insurance who need help paying for treatment with Xofigo are not eligible for co-pay assistance through Xofigo Access Services. These patients may be eligible for co-pay or co-insurance assistance through
an independent co-pay assistance foundation. If co-pay assistance needs are identified, a Xofigo Access Services Access Counselor can provide information about other foundations that will determine a patient’s eligibility for co-pay or co-insurance assistance based on their own criteria.

**REACH**

Call REACH (Resources for Expert Assistance and Care Helpline) Service Counselors for:

- Co-pay assistance for privately-insured patients
- Alternate coverage research for uninsured and underinsured patients
- Referral of qualified patients to charitable organizations for assistance with their out-of-pocket expenses.

For more information, go to reachpatientsupport.com or call 1.866.639.2827.

**Co-Pay Program**

There are two ways to register for this program: 1) through select specialty pharmacy providers or 2) through the REACH program.

Program highlights:

- Currently a $0 co-pay and up to $4,000 per month and up to $16,000 per year per patient for privately-insured patients
- If prior authorizations are delayed or denied, patients will be assessed for temporary patient assistance
- Only privately-insured patients who were not previously enrolled in the REACH Co-Pay Assistance Program are eligible; patients enrolled in Medicare, Medicaid, or any other government-funded programs are not eligible for the co-pay program

**Uninsured or Underinsured Patients**

On approval, eligible patients will be provided a monthly supply of their prescribed therapy for 12 months. Eligibility requirements include, but are not limited to:

- Meeting the financial criteria with proof of income
- Completing the enrollment form, including patient and physician signatures
- Patients must reapply every 12 months (or any time there is a change in status of insurance coverage).

**Referrals for Patients with Federally-Funded Insurance**

Independent charitable organizations may assist patients who cannot afford their prescription medication and/or their out-of-pocket costs. REACH Service Counselors can provide eligible patients information and transfer the right patient to the right organizations. For Medicare patients, REACH will provide information regarding Part D plan options and applications for low-income subsidy. For Medicaid patients, REACH will provide information about the application process and follow-up support if the patient decides to apply for assistance.

**REIMBURSEMENT ASSISTANCE**

**Xofigo Access Services**

Comprehensive reimbursement assistance, including:

- Insurance benefit verifications
- Prior authorization support
- Claims appeal research and information
- Claims tracking
- Billing and coding information
- Payer policy information.

To access these services, call 1.855.6XOFIGO (1.855.696.3446) 9:00 am to 8:00 pm EST, Monday through Friday. You can also access these services online 24/7 through the Xofigo Access Services Provider Portal: xofigoaccessonline.com. Or download these reimbursement tools:


**REACH**

Call REACH Service Counselors for:

- Benefit verification, prior authorizations, denials, and appeal information
- Specialty Pharmacy Provider (SPP)
- Information on Medicare Part D plan
- Medicaid application and enrollment.
**PATIENT ASSISTANCE**

**Solutions Plus™**

This program offers a range of services to help alleviate financial concerns around access. Insurance coverage should not be a barrier to cancer treatment—we will explore multiple options to help a variety of patients afford their treatment, including:

- **Commercially insured patients** who are eligible pay no more than a $25 co-pay per month through the Co-pay Assistance Program. (NOTE: patients must be U.S. residents.)
- **Publicly insured patients** are connected to alternative funding support, which may help offset co-pays, deductibles, or other treatment-related expenses. If denied alternative funding, publicly insured patients may be eligible for BI Cares Foundation support. (NOTE: patients must be U.S. residents.)
- **Uninsured and underinsured patients** who have been denied financial assistance from other foundations may be eligible for free medication through the BI Cares Foundation. (NOTE: patients must be U.S. residents.)

To determine if a patient is eligible for programs offered by or through Solutions Plus, BI Cares Foundation, or other support programs, use the online financial tool at: https://www.gilotrif.com/solutions_plus/access_and_reimbursement_solutions/financial_support_tool.html. Or enroll your patient by calling 1.877.814.3915, 8:00 am to 8:00 pm EST or by downloading the application at: https://www.gilotrif.com/content/dam/internet/pm/gilotrif4/com_EN/documents/PC-GF-0328-PROF%20Solutions%20Plus%20Enrollment%20Form%20Squamous.pdf.

Complete the entire enrollment form with a signed patient authorization form and Gilotrif prescription and fax it to: 1.866.240.4556. Fax confirmation will be provided within 2 hours of enrollment form submission.

To help with Gilotrif treatment initiation and continued adherence, all patients taking Gilotrif will receive a Patient Support Kit (https://www.gilotrif.com/solutions_plus/clinical_supportsolutions/patient_support_kit.html).

This helpful kit includes the following patient resources:
- My Guide patient brochure
- My Diary treatment journal
- Topical lotion and loperamide (OTC) samples

**Gilotrif Dose Exchange™**

https://www.gilotrif.com/solutions_plus/clinical_supportsolutions/gilotrif_dose_exchange_program.html

Gilotrif Dose Exchange is designed to help facilitate dose adjustments. It is offered to patients who meet the following eligibility requirements:
- Serviced through our dedicated specialty pharmacy partner, Accredo, or the Gilotrif Dispense Network
- For patients exchanging ≥9 tablets.

Here’s how the Gilotrif Dose Exchange facilitates transition to new dose:
• Eligible patients sent new dose promptly once their oncologist submits new prescription
• Covers up to 2 dose modifications
• Patients can easily return unused drug using the prepaid envelope that is sent with the replacement dose.

The Exchange also eliminates additional co-pays in a given month:
• Insurers will not be billed, and patients will not be charged a co-pay for replacement drug.

How Gilotrif Dose Exchange™ works:
• Patient serviced through Accredo or the Gilotrif Dispense Network is prescribed a new dosing strength of Gilotrif (afatinib) tablets and ≥9 pills remain in old dose.
• Oncologist provides new prescription to Solutions Plus on the designated enrollment form.
• Solutions Plus confirms Gilotrif Dose Exchange eligibility.
• Accredo or a central pharmacy at Solutions Plus sends new dose and prepaid return envelope to patient; health plan is not billed and patient is not charged a second co-pay for the new prescription.
• Patient returns pills remaining from old dose using prepaid envelope provided by Solutions Plus.

Nurse and Pharmacy Support
Nurse support: Real-time patient education and assistance to complement care. Oncology-trained nurses will call participating Gilotrif patients during critical time points of NSCLC treatment to assist with adherence.
• Five outbound calls will be made to patients
• Treatment-related adverse events education and tips for adherence are addressed
• Language interpreter service available in 170 languages.

Oncology-trained nurses are also available to answer questions as needed. Contact Solutions Plus at 1.877.814.3915, 8 am-8 pm ET. Solutions Plus® keeps your practice informed throughout each patient’s participation in the program. When a nurse speaks to a patient about treatment with Gilotrif, your office receives a fax update.

Pharmacy support: Dedicated Gilotrif professionals are available for patients and physicians who have questions related to Gilotrif. Physicians and healthcare practice professionals may connect directly with Gilotrif-trained pharmacists with Accredo. Call 1.844.569.2837 from 8:30 am to 7 pm ET or fax 1.888.454.8488. Patients can reach Patient Care Advocates and Gilotrif-trained nurses with Accredo by calling 1.844.569.2836 from 8 am to 8 pm ET.

REIMBURSEMENT ASSISTANCE
Solutions Plus
This program helps providers and patients navigate coverage and reimbursement challenges. Knowledgeable reimbursement specialists assist with the coverage and reimbursement process throughout the patient’s Gilotrif treatment journey. To get patients started on therapy as easily and quickly as possible and minimize reimbursement challenges, Solutions Plus provides assistance with:
• Benefit verification. Upon enrollment, reimbursement specialists investigate and verify coverage for patients within 2 business days from initiation.
• Prior authorization. Reimbursement specialists anticipate and communicate prior authorization requirements for payers. If prior authorization is needed and the patient receives Gilotrif tablets from our dedicated specialty pharmacy partner, Accredo, then Solutions Plus may assist with submission and tracking of prior authorization consistent with health plan requirements.
• Gilotrif Bridge. If a patient experiences a payer delay of more than 7 days for the FDA-approved indication, they may receive a 15-day supply of Gilotrif tablets. This program allows patients to start therapy and avoid a prolonged delay.

NOTE: This program is for commercially and publicly insured patients treated with Gilotrif for the FDA-approved indication.
• Denials & appeals. Reimbursement specialists follow up with programs when patient claims are denied, and Boehringer Ingelheim Access Reimbursement and Distribution Managers provide additional support with the appeals process.
Providers can obtain a Solutions Plus enrollment form by calling 1.877.814.3915, 8:00 am to 8:00 pm EST or download the application at: https://www.gilotrif.com/content/dam/internet/pm/gilotrif4/com_EN/documents/PC-GF-0328-PRO%20Solutions%20Plus%20Enrollment%20Form%20Squamous.pdf.

Complete the entire enrollment form with a signed patient authorization form and Gilotrif prescription and fax it to: 1.866.240.4556. Fax confirmation will be provided within 2 hours of enrollment form submission.

**Distribution**

Solutions Plus® works closely with Accredo, our single, dedicated, specialty pharmacy partner, to ensure:
- Timely distribution
- Seamless transition from enrollment to prescription fulfillment
- Consistent support experience for patients.

Gilotrif is also available at select on-site pharmacies:
- Select, large group practices
- Kaiser Permanente®
- NCI-designated Cancer Centers
- Select hospitals with outpatient clinics
- Integrated delivery networks
- Veterans Administration/Department of Defense.

**Gilotrif Pledge™**

https://www.gilotrif.com/solutions_plus/access_and_reimbursement_solutions/gilotrif_pledge_program.html

This program reduces the financial impact often caused by treatment discontinuations by providing patient and payer refund for the first month of therapy if eligible patients discontinue before first refill. Lack of refill triggers Gilotrif Pledge™ program.

This program is offered to patients who meet the following eligibility requirements:
- Commercially insured by participating health plan
- Serviced through our dedicated specialty pharmacy partner, Accredo
- Enrolled in nurse support program (NOTE: Patients are automatically enrolled in the nurse support program when they enroll in Solutions Plus. Patients not serviced through Accredo are able to opt in to the nurse support program if interested.)

How Gilotrif Pledge™ program works:
- For patients serviced through Accredo, a Reimbursement Specialist confirms that patient’s insurer is participating in the Gilotrif Pledge program
- When patient is called to schedule their first refill and indicates discontinuation, a call is placed to the provider’s office to confirm discontinuation
- Solutions Plus refunds patient and payer for entire cost of first month of therapy.
**Oncology-related products:** Empliciti™ (celotuzumab), Ixempra® (ixabepilone), Opdivo® (nivolumab), Sprycel® (dasatinib), Yervoy® (ipilimumab)

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**Bristol-Myers Squibb**

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**Patient and Reimbursement Assistance Website**

bmsaccesssupport.bmscustomerconnect.com/oncology/services/patient-financial-assistance

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**PATIENT ASSISTANCE**

**BMS Access Support™**

Bristol-Myers Squibb (BMS) Access Support can help identify financial assistance programs for eligible patients who need help managing the cost of treatment. The appropriate program will depend on the patient’s coverage.

**BMS Oncology Co-Pay Program**

This program (bmscustomerconnect.com/bmsaccesssupport/oncology/services/patient-financial-assistance/copay) is designed to assist with out-of-pocket co-pay, deductible, or co-insurance costs for eligible, commercially insured patients who have been prescribed certain BMS products. Patients with state or federally-funded insurance plans are not eligible for this co-pay program. Enrolled patients pay the first $25 of their co-pay per infusion. If the patient receives two BMS medications covered by this Program on the same day, the combination of those two medications will be treated as one dose, requiring the patient pay only $25 of the medications’ co-pay for that day. BMS will cover the remaining amount up to $25,000 per year per product, or $50,000 per year for two BMS products administered in combination. Other restrictions may apply. Final determination of program eligibility is based upon review of completed application.

Enrollment is simple. The provider collects the patient’s name, address, insurance carrier, and member identification number. The provider then completes the application through BMS Access Support in one of the following ways:

- Use the BMS Access Support Form Wizard.
- Download the enrollment form on your computer and fax to 1.888.776.2370.
- Enroll online with our secure portal: MyBMSOncologyCases.com.

When completing the form, check the box for the BMS Oncology Co-Pay Program. BMS Access Support determines patient eligibility, including verifying commercial insurance coverage to establish the appropriate benefit amount. BMS Access Support then notifies the provider and patient of enrollment and the appropriate next steps. Finally, the provider submits the primary claim to the commercial insurance carrier. If the Explanation of Benefits form indicates that your patient has a cost-sharing expense, notify BMS Access Support and submit the required documentation to initiate appropriate next steps. For questions or to confirm receipt of the application, call the Support Center at 1.800.861.0048, 8:00 am to 8:00 pm EST, Monday through Friday.

**Assistance for Uninsured Patients**

For patients without prescription drug insurance, or for patients that are underinsured, BMS Access
Support can refer them to independent charitable foundations that may be able to provide financial support, including, the Bristol-Myers Squibb Patient Assistance Foundation (BMSPAF): bmspaf.org. This charitable organization provides medicine, free of charge, to eligible, uninsured patients who have an established financial hardship. The BMSPAF accepts the BMS Access Support application. Patients may be eligible for assistance through the BMSPAF if they:

- Do not have insurance coverage, or have been denied coverage for a requested medicine
- Are enrolled in a Medicare Part D plan and have spent at least 3 percent of their yearly income on out-of-pocket costs for prescription medicines in the current year
- Are being treated on an outpatient basis
- Live in the United States, Puerto Rico, or the U.S. Virgin Islands
- Meet the income limits for the requested medicine.

These are just some of the eligibility requirements. Other eligibility criteria may apply. For more information about eligibility and to obtain an enrollment application, call the Bristol-Myers Squibb Patient Assistance Foundation, at 1.800.736.0003.


BMS Access Support can provide plan-specific prior authorization forms when one is required by the patient’s health plan. Some health insurers require that a prior authorization be issued before certain items or services are covered. This may require specific forms and supporting documents before a prior authorization may be issued (e.g., medical history, physicals, pathology reports, etc.). When necessary, make sure your patients understand coverage for the service before they have a financial obligation to their provider. Please note: If a prior authorization requirement is not met, some health insurers may deny coverage, even if the claim would have otherwise been covered. If coverage is denied, either the physician or the patient may appeal. See below for details on prior authorization appeals.

Some insurers will make a predetermination of coverage decision upon...
request. This generally applies to an item or service that does not require a prior authorization. If a predetermination decision denies coverage, either the physician or patient may appeal the decision with the insurer, in the same manner an appeal can be made on a denial of prior authorization.

For prior authorization assistance from BMS Access Support, providers will need:
- Patient demographics
- Complete insurance information and copy of card
- Physician demographics and signature
- Diagnosis and drug name.

BMS Access Support: Claims Appeal Assistance
Almost all health insurers have a specific process to appeal an unfavorable coverage decision. BMS Access Support can assist in navigating the appeals process. However, the preparation and submission of documents to support the appeal is the responsibility of the patient and/or healthcare provider. Bristol-Myers Squibb and its agents make no guarantee regarding the outcome of appeals assistance. When you’re filing an appeal, keep in mind:

- Coverage decisions may be made by an insurer before the treatment is rendered or after a claim is filed. Coverage decisions that are made before a treatment regimen is initiated are often referred to as “prior authorization” or “coverage determinations.”
- Medicare Part B and many other health insurers will not make a coverage decision regarding individual patients before a claim is filed. Coverage is considered only at the time a claim is presented for payment.
- The billing provider can usually appeal an insurer’s decision to deny coverage for a claim. Appeals are almost always subject to timeliness requirements. The window of time allowed for a provider to appeal an unfavorable coverage decision usually begins on the date a claim was adjudicated (processed) by the insurer.
- If the health insurer approves an appeal, you will be notified and the claim will be reconsidered.
- If the health insurer denies the appeal, contact BMS Access Support for further assistance at 1.800.861.0048.
- Each plan has its own process and timeline for appeals. The appeals process for Medicare Part B contractors is determined by the Centers for Medicare and Medicaid Services (CMS).

More questions? Download the full Reimbursement Guide at: bmscustomerconnect.com/bmsaccesssupport/servlet/servlet.FileDownload?file=00Pi000000AQAiDEAX.
Oncology-related products: Abraxane® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound), Istodax® (romidepsin) for Injection, Pomalyst® (pomalidomide), Revlimid® (lenalidomide), Thalomid® (thalidomide), Vidaza® (azacitidine)

**Patient and Reimbursement Assistance Website**
celgenepatientsupport.com

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**PATIENT ASSISTANCE**

**Celgene Free Medication Program**
The Celgene Free Medication Program is available to qualified patients who are uninsured or underinsured:

- Your patients must meet required insurance and financial criteria
- Celgene Patient Support can also help you find outside programs through which your patient may qualify for financial support.

There are three ways to enroll your patient in Celgene Patient Support.

1. Enroll online at: celgenepatientsupport.com/enrollment.
2. Download the Celgene Patient Support Enrollment Form in English (celgenepatientsupport.com/wp-content/uploads/CPS_Application_Form_English.pdf) or Spanish (celgenepatientsupport.com/wp-content/uploads/CPS_Application_Form_Spanish.pdf) and fax the completed form to 1.800.822.2496, or e-mail the completed form to: patientSupport@celgene.com.
3. Enroll over the phone at 1.800.931.8691, Monday through Friday, 8:00 am to 7:00 pm EST.

**Celgene Commercial Co-Pay Program**
This program is for eligible, commercially insured patients. If qualified, your patient’s out-of-pocket co-pay responsibility will be $25 or less, depending on the Celgene product they have been prescribed. This program provides up to $10,000 per calendar year to help meet deductible, co-pay, and co-insurance costs. Patients must meet specified financial criteria to qualify for assistance. To qualify patients must have:

- Commercial and/or private insurance (Patients with Medicare, Medicaid, or other government-sponsored insurance are not eligible for this program)
- Household income of $100,000 or less (subject to random audit)
- Residence in the United States or Puerto Rico

To learn more call 1.800.931.8691, Monday through Friday, 8:00 am to 7:00 pm EST.

**Third-Party Financial Assistance**
For patients with Medicare, Medicaid, or other government-sponsored insurance, Celgene Patient Support can help explore deductible, co-pay, co-insurance, or premium assistance options with third-party organizations. Celgene Patient Support will walk your patient step-by-step through the process of securing financial support from these third-party organizations. Celgene Patient Support will also help locate transportation assistance options to assist with the costs of traveling to and from the physician’s office. If you have questions call 1.800.931.8691, Monday through Friday, 8:00 am to 7:00 pm EST. You can also view a list of third party organizations that may be able to lend financial assistance.
support to your patient online at: celgenepatientsupport.com/find-financial-help/.

**Successful Start App**
Providers can access Celgene Patient Support services on their mobile device or tablet using the Celgene Patient Support Successful Start App. The Successful Start App allows you to:

- Begin the Celgene Patient Support enrollment for your patients, and request a Patient Support Specialist to call or email them to address specific questions.
- Find and send information about the support available for the specific Celgene medication you are prescribing, including financial and insurance-related support services.
- Find and connect with your Celgene Patient Support Specialist by entering the zip code in which your office is located.
- Patients can also download this app and have access to many of the same services on their mobile devices.

To download the Successful Start App you can either scan the QR code directly to your mobile device, or search for “Celgene Start” in the iTunes App Store or Google Play. The Successful Start App is available for iPhone, iPad, and Android devices. NOTE: These resources are not available for all Celgene products. Patients and caregivers seeking information on a product not included the Successful Start App should contact Celgene Patient Support for Assistance. Call 1.800.931.8691, Monday through Friday, 8:00 am to 7:00 pm EST.

**REIMBURSEMENT ASSISTANCE**

**Celgene Patient Support Specialists**
Providers and patients are assigned a Celgene Patient Support Specialist based on the zip code of the doctor’s office.

The Celgene Patient Support Specialist will work with your patient to resolve access issues to Celgene medications. With continual communication and consistent follow-through, these specialists will streamline access to Celgene products by helping you and your patients with:

- Benefits investigation
- Prior authorization
- Appeals support
- Understanding Medicare or other insurance coverage
- Co-pay assistance (for qualified patients with commercial and/or private insurance)
- Celgene Free Medication Program (for qualified patients who are uninsured or underinsured).

Contact Celgene Patient Support at 1.800.931.8691, Monday through Friday, 8:00 am to 7:00 pm EST. Or send an e-mail to patientSupport@celgene.com. Learn more at: celgenepatientsupport.com.

**Prior Authorization**
Some health insurance plans require prior authorization for the use of Celgene products. At your request, Celgene Patient Support will assist your office staff with the prior authorization process, and follow up with the insurance provider to determine the outcome. You can download the Celgene Patient Support Prior Authorization Checklist at: https://www.celgenepatientsupport.com/wp-content/uploads/Prior-Authorization-Checklist.pdf. Contact Celgene Patient Support at 1.800.931.8691 for assistance with prior authorizations.

**Appeals**
If your patient’s insurance company denies coverage for the Celgene medication you have prescribed, Celgene Patient Support can help facilitate the appeal. During the appeals process your patient may qualify for the Celgene Free Medication Program. (See information about the program and eligibility requirements above.) In order for Celgene Patient Support to assist with the appeal, please provide the following information within two weeks of the insurance denial:

- Copies of the front and back of the patient’s health insurance card(s), including the patient’s drug card or copy of patient’s information sheet clearly identifying insurance information, including phone numbers and claim submission address.
• Denial letter from payer complete with appeal address.
• History and physical or consult letter and progress notes, and if applicable, related laboratory reports. Last three months needed.
• Letter of medical necessity (see below for guidelines). Please include drugs tried and failed for this diagnosis.
• Appointment of representative release form signed by the patient, parent, or guardian. This form allows Celgene Patient Support to act on behalf of the patient during the appeals process.

In addition to helping you and your patient filing the appeal, Celgene Patient Support will follow up on the status of the appeal until a decision is reached. For more information about Celgene Patient Support appeals assistance call: 1.800.931.8691, Monday through Friday, 8:00 am to 7:00 pm EST.

Letter of Medical Necessity

In seeking an appeal from your patient’s insurance company, your Letter of Medical Necessity will be critical to the appeal outcome. Your letter should include a brief history of the patient, with the following information:
• Patient name
• Initial date of diagnosis
• Significant laboratory tests and results
• Specific cell type per pathology report, including documentation of metastasis, if applicable

• Original treatment rendered, including all drugs, dosages, and schedules
• Reason for stopping treatment and the patient’s clinical response.

The current status of the patient, including:
• Date of recurrence, if applicable.
• Recommended treatment plan with specific drugs, dosages, and schedules.
• Rationale for treatment, including unabridged reprints or copies of applicable scientific and medical articles, comprehensive bibliographies, official FDA drug labeling, etc. (Contact Celgene Patient Support if you require assistance preparing this information.)
• Previous drug therapy, including status of specific lifetime maximum drug benefits and/or medical complications resulting from other drug treatment regimens.

PATIENT ASSISTANCE

The Eisai Patient Assistance Program

Certain Eisai medications may be available at low-or-no cost to financially needy patients who satisfy eligibility criteria. To learn more call 1.866.61.EISAI (1.866.613.4724). The same program enrollment form is used for all eligible Eisai products. You can download the form here: http://www.eisaireimbursement.com/-/media/Files/XRay/Aloxi/Patient-Assistance-Enrollment-Form.pdf.

The Eisai insurance verification form (also used for all Eisai medications) can be downloaded here: http://www.eisaireimbursement.com/-/media/Files/XRay/Aloxi/Insurance-verification-form.pdf

Akynzeo Patient Assistance Program

The Akynzeo Patient Assistance Program provides the drug at no or low cost to financially needy patients who meet program eligibility criteria. Download the enrollment application at: http://www.eisaireimbursement.com/-/media/XRay/Akynzeo/Akynzeo-pap-enrollment-form.pdf and fax the completed form to: 1.866.57.EISAI (1.866.573.4724). Questions? Call 1.866.61.EISAI (1.866.613.4724), Monday through Friday, 8:00 am to 8:00 pm EST. Similar programs are available for some of Eisai’s other oncology-related products. For a complete list of Eisai medications and the level of patient assistance available for these medications visit: http://www.eisaireimbursement.com/.

Pay $0 Savings Program

Commercially insured patients prescribed certain Eisai medications may be eligible for the Eisai Pay $0 Savings Program. Under this program commercially insured patients pay a $0 co-pay on each prescription with an annual limit. Limits vary depending on the Eisai medication you have prescribed.

• For patients prescribed Akynzeo, there is an $1,800 annual limit. For cash pay patients, Eisai Inc. will pay up to $150 per prescription for a maximum benefit of $1,800 per year.

• For patients prescribed Halaven, the maximum benefit paid by Eisai Inc. will be $18,000 per year.

• For patients prescribed Lenvima, Eisai Inc. provides up to $40,000 per year to assist with out-of-pocket costs.

The enrollment process also varies depending on the Eisai medication that has been prescribed.

If you have prescribed Akynzeo and your patient’s insurer covers this medication under the medical benefit, call 1.866.61.EISAI (1.866.613.4724) to enroll your patient in the medical benefit savings card program.
Eisai

If you have prescribed Lenvima, no activation or enrollment is required. Call your patient’s specialty pharmacy for details.

If you have prescribed Halaven there is a multi-step enrollment process, outlined below:

Step 1: Complete and submit an enrollment form (http://www.eisaireimbursement.com/-/media/XRay/Halaven/Halaven-0Copay-Enrollment-Form.pdf) signed by both you and your patient.

Step 2: If the patient is determined to be eligible they will be sent a Welcome Letter and a card. This card should be given to your office so that it can be used to process the virtual debit card payment.

Step 3: Fax the Explanation of Benefits (EOB) or detailed Specialty Pharmacy receipt for the Halaven claim to 844.745.2350. The following information should be included:

- Patient's information including full name
- Date of service
- Cost of the medication
- Amount covered by the insurance
- Patient's responsibility: deductible; co-payment; and co-insurance.

Step 4: If the patient’s claim is approved, the appropriate funding based on the patient’s out of pocket costs will be loaded onto the patient’s card and a confirmation letter will be sent to you and your patient.

Restrictions and Conditions

Eligibility Criteria: Good toward the purchase of prescribed, eligible Eisai medication. No substitutions permitted. Save this card to reuse with each prescription. Not available to patients enrolled in state or federal healthcare programs, including Medicare, Medicaid, Medigap, VA, DoD, or TRICARE. May not be combined with any other coupon, discount, prescription savings card, free trial, or other offer. Federal law prohibits the selling, purchasing, trading, or counterfeiting of this card. Such activities may result in imprisonment of 10 years, fines up to $25,000, or both. Void outside the U.S. and where prohibited by law. Eisai Inc. reserves the right to rescind, revoke, or amend this offer at any time without notice. Patients and pharmacies are responsible for disclosing to insurance carriers the redemption and value of the card and complying with any other conditions imposed by insurance carriers or third-party payers. The value of this card is not contingent on any prior or future purchases. The card is solely intended to provide savings on any purchase of the approved Eisai medication. Use of the card for any one purchase does not obligate the patient to make future purchases of the same Eisai medication or any other product. For patients prescribed Akynzeo, this offer is available to MA residents through June 30, 2017, and to all other patients through March 31, 2020. For patients prescribed Halaven, this offer will expire November 20, 2019.

Reimbursement Assistance

The Eisai Assistance Program

This program is your dedicated resource to help you answer your coverage questions. The Eisai Assistance Program provides you with information about payor-specific coverage policies for the Eisai medication(s) you have prescribed, billing and coding requirements, and alternative financial assistance options for your patient. What to expect when you contact the Eisai Assistance Program:

- Product specific reimbursement information
- Understanding of coverage, coding and payment issues
- Payer policy information.

The Eisai Assistance Program offers providers a wide range of online tools for each of its products, including:

- Product information
- Billing forms
- ICD-10-CM diagnosis codes
- ICD-10-CM Supplementary Classification Codes
- CPT drug administration codes
- HCPCS Level II code
- National drug codes
- Revenue codes
- Medicare reimbursement rates
- A checklist for claims submission.

Questions? Contact the Eisai Assistance Program at 1.866.61.EISAI, Monday through Friday, 8:00 am to 8:00 pm EST.
Oncology-related products: Alecensa™ (alectinib), Avastin® (bevacizumab), Cotellic™ (cobimetinib) tablets, Erivedge™ (vismodegib), Gazyva™ (obinutuzumab), Herceptin® (trastuzumab), Kadcyla® (ado-trastuzumab emtansine), Perjeta™ (pertuzumab), Rituxan® (rituximab), Tarceva® (erlotinib), Tecentriq (atezolizumab injection), Venclexta (venetoclax tablets), Xeloda® (capecitabine), Zelboraf® (vemurafenib)

**Patent and Reimbursement Assistance Website**
genentech-access.com

**Patient Assistance**

**Genentech Access Solutions**

The Genentech Access to Care Foundation

GATCF was created to help qualified patients receive certain Genentech medicines free of charge. GATCF might be able to help patients receive treatment if they meet specific financial and medical criteria.

For patients that are uninsured, or have been rendered uninsured by payer denial:

- The patient’s annual household adjusted gross income (AGI) must be $100,000 or less, or patient’s annual household AGI must be between $100,000 and $150,000 and the out-of-pocket costs for his or her Genentech medicine accounts for at least 5 percent of his or her annual household AGI
- All patient assistance options, including Genentech brand-specific co-pay cards and support from co-pay assistance foundations, have been exhausted
- The patient meets medical criteria determined by the GATCF Clinical Advisory Board.

For insured patients who have coverage for their Genentech medicine:

- Patient annual household adjusted gross income (AGI) must be $150,000 or less and the out-of-pocket costs for his or her Genentech medicine accounts for at least 5 percent of his or her annual household AGI
- The patient meets medical criteria determined by the GATCF Clinical Advisory Board.

To apply to GATCF, the following forms must be completed and submitted:

1. The Statement of Medical Necessity (SMN) form.
2. The Patient Authorization and Notice of Release of Information (PAN) form in English or Spanish.
3. The GATCF Insurance Attestation form.
5. The confirmation of Infusion or Injection form (if applicable).

Forms can also be e-submitted online through the Genentech’s Forms and Documents page specific to your Genentech medication. Forms are drug-specific, so you must follow the prompts at: genentech-access.com to access the correct forms. Questions? Call Access Solutions at: 888.249.4918, Monday through Friday, 6:00 am to 5:00 pm PST.

NOTE: Eligible patients with a Medicare Part D plan who do not qualify for support from a co-pay assistance foundation may receive certain Genentech medicines free of charge provided they meet the eligibility criteria for insured patients outlined above.
Genentech BioOncology™
Co-pay Card
This Co-pay Card helps patients with the out-of-pocket costs of their prescription. Qualified patients must:
• Be covered by commercial or private insurance
• Be receiving treatment that is consistent with the FDA-approved use of the Genentech therapy
• Not participate in a government funded healthcare program, such as Medicare, Medicaid, Medigap, VA, DoD, or TRICARE
• Be 18 years of age and older
• Currently live and receive treatment in the United States or Puerto Rico
• There is no income requirement for the Genentech BioOncology Co-pay Card Program.

NOTE: Patients receiving funding from the Genentech Access to Care Foundation are not eligible for the Genentech BioOncology Co-pay Card Program. Some health plans might not accept a co-pay card. Patients should contact their insurance providers to find out if their plan allows the use of co-pay cards.

Under the Genentech BioOncology Co-pay Card Program, the patient is responsible for a $25 co-pay per prescription or infusion. The annual benefit limit of the co-pay card is $25,000. Retroactive requests for assistance from the BioOncology Co-pay Card program may be honored if the infusion or prescription fill occurred within 120 days prior to enrollment, and the patient met eligibility requirements when the Genentech product or service was received. Patients do not need the physical card to receive benefits; they just need their ID code. If a patient is taking more than one Genentech cancer medicine, these benefits apply to each medicine individually. Need help with enrollment? Call 855. MYCOPAY (855.692.6729), Monday through Friday, 9 am to 8 pm EST, or visit copayassistancenow.com.

Referrals to Co-pay Assistance Foundations
If patients need help with their medication co-pays, Access Solutions can connect them to co-pay assistance foundations supporting their disease state. Genentech does not influence or control the operations of these co-pay assistance foundations, but Access Solutions can assist patients by making an appropriate referral to a foundation that may be able to help. Genentech cannot guarantee co-pay assistance once a patient has been referred by Access Solutions. The foundations to which patients are referred will have their own criteria for patient eligibility, including financial eligibility.

REIMBURSEMENT ASSISTANCE
Genentech Access Solutions
Benefits Investigation
Access Solutions conducts a benefits investigation (BI) to help you better understand your patient’s health plan coverage for some or all of the costs associated with treatment. The BI can also determine if a prior authorization or patient assistance might be needed. To have Access Solutions conduct a BI, providers must request the assistance on the signed SMN form. There are three possible outcomes of a BI:
1. Treatment is covered
2. Prior authorization is required
3. Treatment is denied.

To begin with Access Solutions, you must complete and submit the Statement of Medical Necessity (SMN) form and have your patient complete and submit a Patient Authorization and Notice of Release of Information (PAN) form. The SMN can be submitted online via My Patient Solutions: gene.secure.force.com/ihcp/GNE_CM_MPS_Login or download at genentech-access.com. Forms are drug-specific, so you must follow the prompts to access the correct forms. Patients can submit the PAN online at: pan.iassist.com/forms/bioonc or download it online at: genentech-access.com. Forms are drug-specific, so you must follow the prompts to access the correct forms.

Prior Authorization Assistance
Access Solutions can help providers identify whether a prior authorization (PA) is needed and help them secure it. Simply complete and sign a SMN form requesting assistance with the PA, as well as a signed and dated PAN form (see instructions above). Access Solutions can help providers submit the required PA forms and documentation. If the PA is not granted, Access Solutions can work with providers to determine next steps.
**Appeals**

If providers have prescribed a Genentech product but an insurer has denied coverage, they can appeal that decision. Access Solutions might be able to help providers resolve the situation. Here is what you can do:

1. Understand why the request or claim has been denied. This should be in the insurer's letter of denial or the patient’s Explanation of Benefits (EOB) letter.

2. Contact Access Solutions for guidance as you put together an appeal. Use the resources provided to help you gather the documents and information you need for a successful appeal.

3. Complete and submit the required forms and documents to the insurer before the appeal deadline. Access Solutions can provide information about this process.

Here is a checklist of the forms and documents you may need for an appeals package if an insurer denies treatment to your patient.

**NOTE:** Each insurer and each patient might need different information. Please review each denial and the insurer's guidelines, as well as this website, to determine what to include in your patient’s appeals package.

- Statement of Medical Necessity
- Patient Authorization and Notice of Release of Information
- Copy of the patient’s health plan or prescription card (front and back)
- Appeal letter
- Denial information including the patient’s denial letter or Explanation of Benefits letter
- Supporting documentation:
  - Patient history and physical findings
  - Healthcare provider’s chart notes
  - List of current medications, with dose and frequency
  - List of treatments tried without success
  - Test and lab results
  - Hospital admission/emergency department notes.
- Other supporting documents, including journal articles, abstracts, textbook excerpts, practice guidelines, and/or compendia indications.

**My Patient Solutions™**

My Patient Solutions allows you the flexibility to work with Genentech Access Solutions online whenever you need. Features of My Patient Solutions:

- Paperless enrollment: Enroll your patients entirely online using electronic signatures.
- Full benefits investigation reports: Review benefits investigation reports for all your patients enrolled in Genentech Access Solutions.
- Patient case management: Search for open or closed cases initiated online or via fax for easier patient case management, re-enrollment or recertification.
- Customized alerts: Customize which email alerts you receive about a patient’s case status so you know what actions need to be taken.

To register your program or practice, you will need the following information:

- Primary Genentech products prescribed by your program or practice
- User information including email addresses (you may add additional users at a later date)
- Program or practice location information (you may add additional locations at a later date)
- Prescriber licensing information, including: a Prescriber National Provider Identifier and State license number (required).

Providers will be asked to agree to the My Patient Solutions Practice Agreement. They must agree to these terms to proceed with My Patient Solutions. For support, call 866.4ACCESS (866.422.2377), 6:00 am to 5:00 pm PST, Monday through Friday. Learn more at: https://www.genentech-access.com/hcp/learn-about-our-services.html.
Incyte Corporation

Oncology-related products: Jakafi® (ruxolitinib) tablets

Patient and Reimbursement Assistance Website
incytecares.com

PATIENT ASSISTANCE

IncyteCARES
IncyteCARES (Connecting to Access, Reimbursement, Education and Support) offers ongoing support and resources to patients being treated with Jakafi (ruxolitinib), including:

• Prescription insurance verification and prior authorization support
• Free drug and co-pay assistance, for those who qualify
• Referral to independent nonprofit organizations or foundations that may be able to provide financial assistance
• Access to oncology nurses.

Enrollment is easy. Download the enrollment form at: incytecares.com/pdf/jakafi-enrollment-form.pdf.

NOTE: Providers and patients must work together to fill out the enrollment form. Completed forms should then be faxed to: 1.855.525.7207. In most states, the enrollment form will serve as the patient’s initial prescription for Jakafi. By signing the form, the patient is automatically enrolled in the Access, Reimbursement, Education and Support services. If patients are not interested in signing up for these services, they may opt out. Once IncyteCARES receives the form, it will confirm the patient’s prescription drug coverage and then coordinate with a specialty pharmacy to fill the prescription. The specialty pharmacy will then contact the patient to make delivery arrangements. Then IncyteCARES will determine whether patients qualify for additional services, such as co-pay or free product assistance.

Uninsured Patients
Patients who do not have prescription drug coverage for Jakafi may be eligible to receive the drug free of charge through the IncyteCARES patient assistance program. This program helps people who do not have a prescription drug plan, as well as those whose plans have turned them down for Jakafi treatment. Certain conditions apply for prescription savings. Patients may be eligible if they are a resident of the U.S. or Puerto Rico and their household size and annual income meet certain criteria, including earning less than $125,000 a year or less than 600% of the Federal Poverty Level (FPL). In addition, patients insured through Medicare, Medicaid, TRICARE, and healthcare exchange plans are not eligible. An IncyteCARES specialist can help determine if patients qualify for patient assistance. Call 1.855.4.Jakafi (1.855.452.5234) to learn more. Terms of the program are subject to change.

Co-pay Assistance
If patients are eligible, the co-pay assistance plan for Jakafi may be able to reduce their co-payment to as little as $25 per month. Patients may be eligible for co-pay assistance if they have commercial or private insurance, they are a resident of the U.S. or Puerto Rico, they are 18 years of age or older, and they have a valid prescription for Jakafi for an FDA-approved treatment. Uninsured, cash-paying patients are not eligible. Not valid for patients covered under state or federally-funded healthcare programs, such as Medicare, Medicaid, or TRICARE. Patients must have minimum out-of-pocket cost of $25.01 to redeem this card and must contribute $25 towards that out-of-pocket cost. Patients
must disclose the use of the co-pay card to their insurers. The amount of savings on Jakafi will not exceed $10,000 per month and $25,000 per year. Limit one 30-day supply per 30 days. Card is valid for one year after activation, after which time a card must be reactivated to continue use. Call 1.855.4.Jakafi (1.855.452.5234) to learn more. Terms of the program are subject to change.

**Temporary Access**

Eligible patients experiencing coverage delays greater than 3 business days can receive a free 30-day supply of Jakafi. To qualify, patients must provide proof of insurance claim form submission.

**Referral to an Independent Non-profit Organization**

If patients are not eligible for one of the IncyteCARES prescription savings programs, IncyteCARES may refer them to other resources, such as independent non-profit organizations and co-payment assistance foundations that may be able to help with their co-payment. Each of these organizations has its own set of rules, and Incyte does not influence or control them in any way. To apply to a foundation, patients will need to gather some information, including:

- All of the patient’s medical conditions and treatments.
- The provider’s name, address, telephone number, and fax number.
- The patient’s healthcare plan information. Patients should have their insurance card ready when they contact IncyteCARES. If they have more than one healthcare plan, have all the information ready.
- The amount of the co-pay, if the patient knows this information.
- The patient’s household income. If possible, patient should have supporting documentation such as a pay stub, tax return, or disability form on hand.

After being referred to a foundation, patients will need to fill out an application. Here are some questions they might want to ask the foundation to get started:

- How long does the approval process take after I apply for help?
- How will I be told if I am approved for or denied help from you?
- Will my doctor also be told what you decide?
- If I am approved, where are the payments sent?
- How long can I expect to receive this help?

Each application requires patients to verify their financial needs. It can take from two weeks to 30 days for a foundation to review an application. If patients are turned down by one foundation, IncyteCARES may be able to refer them to another organization.

**REIMBURSEMENT ASSISTANCE**

**IncyteCARES**

A trained IncyteCARES specialist will work with providers and patients to provide assistance with prescription drug plan requirements that must be met before patients can get access to Jakafi. Some healthcare plans may require prior authorization, which means they will ask for more information from the provider before deciding to pay for the patient’s Jakafi. IncyteCARES will work with physicians to provide the necessary information to their patient’s healthcare plan. In addition, if a healthcare plan will not pay for Jakafi, IncyteCARES can help providers and patients understand what needs to be provided to the healthcare plan to appeal the denial. While IncyteCARES cannot apply for the appeal, it can help providers and patients determine the steps they may need to take to overturn the denial. If patients experience insurance coverage delays, IncyteCARES may be able to provide access to Jakafi. Eligible patients who have been prescribed Jakafi for an FDA-approved indication, and who are experiencing an insurance coverage delay greater than three business days, can receive a free, 30-day supply of Jakafi after proof of claims submission is provided. The free product is offered to eligible patients without any purchase contingency or other obligation. For more information, contact IncyteCARES.
Insys Therapeutics

PATIENT ASSISTANCE

Co-Pay Savings Program

The Subsys Savings Program—similar to a coupon—can offer patients free product and up to $1,000 off each additional prescription of Subsys (fentanyl sublingual spray). This program is for commercially insured and cash-paying patients only. Any patient for whom any part of any prescriptions for Subsys is or will be covered by Medicaid, Medicare (including Medicare Advantage or Part D Prescription Plans), any state’s prescription drug programs, or any other public payer program is not eligible for this co-pay program. If any other part of a patient’s prescription is paid by a non-governmental third-party payer, the patient must attest to having disclosed this offer to the third-party payer.

Enrollment is easy. Patients simply complete a short form on the Subsys patient reimbursement and assistance website: subsysspray.com/what-is-subsys/copay-savings-program. Patients can then download their Subsys Savings Card directly from the site. If patients have activated a co-pay savings card and are not taking advantage of the $1,000 off each prescription, they should call 1.855.766.6502 to check their activation status and obtain their member ID number. Only one card per patient can be activated.

REIMBURSEMENT ASSISTANCE

Prescriber Prior Authorization Support

Reimbursement assistance and free product is available for patients during the prior authorization process. To participate, providers simply need to “opt-in” to the Insys Reimbursement Center program by completing the prior authorization assistance form at: subsysspray.com/prior-auth-co-pay-assist. (NOTE: Free product not available for Medicare, Medicaid, and TRICARE patients. Prior Authorization Assistance is available for all insured patients.)

Next a dedicated team of prior authorization specialists will assist providers throughout the prior authorization process—all the way up to and including external review. Healthcare providers are responsible for providing any medical necessity justifications. Questions? Call 1.888.280.5732.
IPSEN Biopharmaceuticals

Oncology-related products: Somatuline® Depot (lanreotide) Injection

Patient and Reimbursement Assistance Website
ipsencares.com

PATIENT ASSISTANCE

Ipsen CARES
The Ipsen CARES (Coverage, Access, Reimbursement & Education Support) program provides free medication to eligible patients through its Patient Assistance Program. Ipsen CARES will determine patient’s eligibility for free product after the enrollment process has been completed. Patients can call 866.435.5677, Monday through Friday, 8:00 am to 8:00 pm EST, to begin the enrollment process. You can also enroll patients online at: https://ipsencare-portal.biologicsinc.com/Account/Login or download the drug specific enrollment form (http://ipsencares.com/downloads/SMD-US-000343%20Somatuline%20Depot%20Enrollment%20Form%20Electronic%20February%202016%20FINAL.pdf) and fax the signed and completed form to 888.525.2416. Ipsen CARES offers the following services for patients:
• Help minimize delays or interruptions in treatment
• Provide financial assistance, including: co-pay assistance (referring eligible patients to Somatuline® Depot Co-Pay Program or an independent non-profit organization) with free product for eligible patients under the Ipsen CARES Patient Assistance Program
• Coordination of specialty pharmacy delivery
• Arrange for eligible patients to have a home health administration nurse visit their home to administer injections at no additional cost to the patient
• Benefits verification and reimbursement support.

Somatuline Depot Virtual Co-pay Savings Program
Patients who are enrolled in Ipsen CARES and are beginning or currently receiving treatment with Somatuline Depot for an FDA-approved indication, who have commercial insurance that covers the medication and associated costs, or are uninsured and paying their entire out-of-pocket cost, may be eligible for the Somatuline Depot Virtual Co-pay Savings Program. Under this program, most eligible commercially insured patients pay no more than $5 per prescription. Program exhausts after 12 months, 13 injections, or a maximum benefit of $20,000, whichever comes first. Patients must enroll annually to receive a continued benefit. Cash paying patients may receive up to $1,666.66 of support per prescription, subject to the annual maximum of $20,000. There are five steps for patients enrolled in Ipsen CARES to receive their Somatuline Depot savings:
2. Provider submits claim to patient’s insurance company.
3. Patient and provider receive Explanation of Benefits (EOB) statement; patient and/or physician mails or faxes EOB to Ipsen CARES at 844.745.2352.
4. Ipsen CARES program coordinator reviews EOB, faxes Somatuline Depot card details to the provider.
5. Physician’s office uses the Somatuline Depot card fax to pay for the patient’s medication.
NOTE: This program is not available to individuals enrolled in federal or state subsidized healthcare programs that cover prescription drugs, including Medicare (such as Medicare Part D prescription drug benefit), Medicaid, TRICARE, or any other federal or state healthcare plan, including pharmaceutical assistance programs. This offer is only available in the U.S. and Puerto Rico, and is restricted in certain states. This offer may not be combined with any other coupon, discount, prescription savings card, free trial, or other offer.

**REIMBURSEMENT ASSISTANCE**

**Ipsen CARES**

Ipsen CARES offers the following Reimbursement Assistance services to patients and providers:

- **Benefits Verification**: Ipsen CARES will help determine patient’s coverage, coverage requirements, and co-payment or co-insurance amount
- **Prior Authorization**: Ipsen CARES will provide information on documentation required by payers, and make recommendations for next steps based on payer policy
- **Appeals Support**: Ipsen CARES will provide information on the payer specific process required to submit a level I or a level II appeal as well as provide guidance as needed throughout the appeals process.

Visit ipsencares.com for more information. Questions? Call 866.435.5677, Monday through Friday, 8:00 am to 8:00 pm EST.

### Benefits Investigation Assessment Form

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Oncology-related products: Darzalex™ (daratumumab), Doxil® (doxorubicin HCl liposome injection), Procrit® (epoetin alfa), Sylvant® (siltuximab), Yondelis® (trabectedin), Zytiga® (abiraterone acetate)

Patient and Reimbursement Assistance Website
janssenprescriptionassistance.com

Janssen Biotech, Inc.

PATIENT ASSISTANCE

Janssen Prescription Assistance
janssenprescriptionassistance.com

This site can help providers:

• Find available support programs. Janssen has collected the available assistance programs for all Janssen products and compiled them on this website.

• Explain program requirements. Most financial assistance programs require patients to have a specific type of insurance coverage to be eligible. The programs listed on each drug page can be filtered by the type of insurance coverage patients have to help narrow your focus. The site also lists as much as possible about other eligibility criteria that each program requires, and the types of information you will need to collect to complete an application.

• Direct you to program applications. In order to make sure the information on this site is timely and accurate, some information, like program applications, is not included. The site does include direct links to each program site so you can learn more details about the program offerings and requirements before you apply. The site’s ultimate goal is to set you on a path toward finding the assistance you need from programs that are best suited to help you. Because living with disease can be difficult. Paying for your medications shouldn’t be.

Johnson & Johnson Patient Assistance Foundation (JJPAPF)

This non-profit organization provides free prescription medications to individuals who are uninsured, or do not have adequate financial resources to pay for their medication. The medications are donated by the operating companies of Johnson & Johnson, including Janssen Biotech, Inc. The Foundation offers the following features:

• One application for all products
• No fee to apply
• Free medicines for up to one year, patients can reapply on a yearly basis

• Healthcare providers and patients work together to fill out and submit a program application
• If approved, patients may receive their medication either directly from their healthcare provider, at a local or mail order pharmacy using their Pharmacy Card, or the medication will be mailed to their home. How patients receive their prescription depends on the medication prescribed. If approved, patients will receive a letter from JJPAPF notifying them of how they will receive their medication.

Patients may be eligible for the Johnson & Johnson Patient Assistance Foundation program if they:
1. Are uninsured, or have been prescribed a medication not covered by insurance; some Medicare Part D patients who cannot afford their medications, and who meet certain financial criteria, may also be eligible for the program
2. Reside in the U.S. or a U.S. territory
3. Are being treated by a licensed U.S. doctor
4. Are being treated as an outpatient
5. Meet the income eligibility for the products listed here: jjpaf.org/eligibility/requirements.html.

Patients can either download the enrollment form via the foundation website at: jjpaf.org/resources/jjpaf-application.pdf or call 1.800.652.6227 to have an application faxed or mailed to them. Completed applications should be faxed to: 1.888.526.5168. Or mailed to: Johnson & Johnson Patient Assistance Foundation, Inc., Patient Assistance Program, P.O. Box 221857, Charlotte, NC 28222-1857.

A provider portal (jjpafportal.org) allows healthcare providers to manage their patients enrolled in the JJPAP Patient Assistance Program. Providers can submit applications, check enrollment status, track shipments, and perform important business functions that would have otherwise required them to phone or fax the program.

NOTE: Eligible hospitals may receive medications to distribute directly to eligible outpatients via the Hospital Access Patient Assistance Program. More information about the eligibility requirements can be found here: jjpaf.org/hcp/access.html.

Questions? Patient assistance specialists are available at: 1.800.652.6227, Monday through Friday, 9:00 am to 6:00 pm EST.

**REIMBURSEMENT ASSISTANCE**

**Janssen CarePath**
https://www.janssencarepath.com/bcp

Janssen CarePath is a source for resources focused on access, affordability, and treatment support for patients. Providers and patients have the flexibility to choose which support and resources they want to use. Janssen CarePath can:

- Conduct a benefits investigation and provide you and your patient with coverage information
- Provide prior authorization support if needed
- Identify financial assistance options for eligible patients
- Assign a dedicated Care Coordinator to you and your patient.

Additional resources available via Janssen CarePath include:

- Billing and coding support for providers, including information on the new ICD-10 billing codes
- Quick links to important forms and documents such as the Janssen CarePath Benefits Investigation Form
- Information on commercial payers, including links to payer-specific prior authorization forms (NOTE: Since information varies by payer, it is important to contact your patient’s payer directly, or to consult the payer website to obtain the most up-to-date, product-specific coverage information)
- General information on the prior authorization appeals process.

For more information, call 877. CarePath (877.227.3728), Monday through Friday, 8 am to 8 pm EST, or visit www.janssencarepath.com.

**SylvantOne™ Support Services**

SylvantOne Support Services (http://www.sylvant.com/for-patients/sylvantone-support-services) is a comprehensive, personalized support program designed to help make access to Sylvant® (siltuximab) simple, convenient, and easy.

**Support for Patients**

- Explanation of insurance benefits and potential medication out-of-pocket expenses.
- Information on the SylvantOne Patient Rebate Program for eligible commercial patients to assist them with their medication out-of-pocket costs. Learn more at: sylvant.com/shared/product/sylvant/sylvant-patient-rebate-program.pdf.
- Assistance with other cost support options, such as a patient assistance program for eligible uninsured patients. Learn more at: sylvant.com/shared/product/sylvant/sylvant-cost-support-options.pdf.
- Access to educational materials and information related to Sylvant.
- Access to personalized appointment reminders, which can help patients remember their next scheduled appointment.
Getting Started


2. For each patient appropriate for treatment with Sylvant, complete a benefit investigation form: sylvant.com/shared/product/sylvant/sylvant-benefit-investigation-form.pdf.

3. Fax the completed forms to 1.855.299.8845.

Questions? Call 1.855.299.8844, Monday through Friday, 8:00 am to 8:00 pm EST.

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**Insurance Verification Form**

Update  [  ]  New  [  ]  Patient Name: ______________________________ ID/SSN #: __________________

Patient Insurance ID: ___________ Group Policy #: ___________ Insurance Company: ___________


Name of Contact: __________________________ Name of Contact: __________________________

Date/Time of Auth: __________________________ Date/Time of Auth: __________________________

Phone/Fax/Address for Auth: __________________________ Phone/Fax/Address for Auth: __________________________

Effective Date: __________________________ PCP: __________________________ Tel #: __________________________

Specific Pharmacy Requirement: __________________________ [  ] Mail order: __________________________

Co-insurance/Co-pay: __________________________ Cap for drugs or diagnosis: $ __________________

Catastrophic Coverage or Stop-loss When? __________________________


Does policy include a Deductible? [  ] Yes  [  ] No  Co-insurance? [  ] Yes  [  ] No  Prescription Drugs? [  ] Yes  [  ] No  Shares of Cost? [  ] Yes  [  ] No

Medicaid? [  ] Yes  [  ] No  Pending? __________________________ Spend Down? [  ] Yes  [  ] No  Medicaid? [  ] Yes  [  ] No  Pending? __________________________ Spend Down? [  ] Yes  [  ] No

Spend Down Amount $ __________________________

Source. The ACCC Financial Advocacy Network. accc-cancer.org/FAN.
Lilly Oncology

Oncology-related products: Alimta® (pemetrexed for injection), Cyramza (ramucirumab), Erbitux® (cetuximab), Gemzar® (gemcitabine for injection), Portrazza™ (necitumumab)

**PATIENT ASSISTANCE**

**Lilly Cares**

Lilly Cares (lillycares.com) is the collection of Lilly patient assistance programs that offer assistance to help people obtain the Lilly medicines they need. This site includes all of Lilly’s patient assistance programs with individual program details. Finding programs that offer Lilly medicines for free or provide reimbursement assistance is easy with the Program Tool Finder: lillycares.com/FindProgram.aspx. The finder tool allows patients and providers to search for an appropriate program one product at a time. Just answer a few questions to see which program may be right for your patient.

**Lilly PatientOne**

Lilly PatientOne (lillypatientone.com) provides a resource for access and reimbursement assistance. Through Patient One, you may be able to help your qualified patients get the assistance they need, allowing them to start treatment with one less worry. Your uninsured, underinsured, or insured patients may qualify for the Patient One Patient Assistance Program if they meet eligibility requirements, including:

- Patient is being administered a Lilly Oncology drug in the United States.
- Patient has proof of residency in the U.S. or Puerto Rico.
- Patient has no medical insurance or the insurance does not cover therapy. If insured, patient must have been denied coverage after two rounds of appeals.
- Patient income is at or below 500 percent of the federal Poverty Level. (NOTE: Federal Poverty Level depends on family size.)
- Patient is in ongoing therapy.
- The date of service is within 180 days of the date of application approval.
- Treatment is or will be provided in an outpatient setting (provider is community-based billing on CMS-1500 or outpatient-facility billing on UB-04).

If you have questions about patient eligibility requirements, PatientOne program specialists are available Monday through Friday, 9:00 am to 7:00 pm EST. Call 1.866.4PatOne (1.866.472.8663).

**Uninsured Patients**

Lilly PatientOne may be able to connect qualified, uninsured patients earning up to 500 percent of the Federal Poverty Level with a Lilly Oncology product at no cost for ongoing therapy. (NOTE: Federal Poverty Level depends on family size). If your patient has been prescribed a Lilly Oncology product and meets the basic points of eligibility:

1. Download and complete PatientOne Application Form: lillypatientone.com/assets/pdf/patient_assistance_program_application.pdf.
2. If applicable, also complete the Dosage Tracking form: lillypatientone.com/assets/pdf/dosage_tracking_form.pdf, and/or the Certification of Brand...
Drug Usage form: lillypatientone.com/assets/pdf/Certification_of_BrandDrug Usage.pdf. (Be sure to check the appropriate box on the application for the Patient Assistance Program.)

3. Once completed, fax the forms and proof of income to 1.877.366.0585.

4. Once the application and appropriate documentation have been submitted and reviewed, you will be notified of your patient’s application status. If approved:
   - Eligible patients will be enrolled into the Patient Assistance Program
   - Approved dates of service will be determined based on the submitted Dosage Tracking Form
   - Lilly PatientOne may send replacement vials for ongoing therapy to your office for approved patients.
   - Lilly PatientOne may evaluate the availability of alternate funding options if needed.

Learn more at: lillypatientone.com/financial-assistance-for-cancer-patients.html.

**Underinsured Patients**
Lilly PatientOne offers co-pay and co-insurance assistance to eligible, underinsured patients. For patients who meet the eligibility requirements listed above, download and complete a copy of the PatientOne Application Form, or call 1.866.4PatOne (1.866.472.8663) to request a copy of the application be sent to you. Fax the completed form to 1.877.366.0585.

As you fill out the form be sure to check all services that your patient might need including any available co-pay program for the prescribed Lilly Oncology product and the Patient Assistance Program in case additional help is needed. Upon receipt of the application, Lilly PatientOne may:
   - Assess the patient’s needs and PatientOne’s ability to help
   - Conduct a benefits investigation to help verify coverage and patient financial responsibility for eligible products
   - Provide information on available co-pay assistance programs
   - Refer you to a charitable co-pay assistance foundation upon request.
   - Review the patient’s eligibility for the Patient Assistance Program if additional help is needed.

If your patient meets the eligibility requirements for the Patient Assistance Program, Lilly PatientOne may send replacement vials to your office for ongoing therapy. You may need to submit a Dosage Tracking form, if applicable. If these additional forms are required, please fax them to 1.888.242.6230.

**Insured Patients**
Even if your patient is fully insured, a claim may still be denied. Lilly PatientOne offers benefits investigation and appeals assistance to qualified, insured patients. If a patient’s claim is eligible, download and complete a PatientOne Application Form, or call 1.866.4PatOne (1.866.472.8663) to request a copy of the application be sent to you. Fax the completed form to 1.877.366.0585. As you fill out the form be sure to check all services that your patient might need including Patient Assistance Program, in the event your patient’s claim is denied. The treating physician will receive a response from PatientOne on the patient’s application has been reviewed.

Lilly PatientOne may:
   - Conduct a benefits investigation to help verify coverage.
   - Provide prior authorization requirements for the patient’s insurer.
   - Provide templates, forms, and checklists for filing an appeal for denied claims for eligible Lilly Oncology products. (These forms can also be found online in the “forms” section of the Lilly PatientOne website).
   - Upon request provide status updates for appeals that have been filed for eligible Lilly Oncology products.

If the appeals process does not result in a favorable decision, after all appeals have been exhausted, Lilly PatientOne will review the patient’s eligibility for the Patient Assistance Program. You may need to submit a Dosage Tracking form, if applicable. If these additional forms are required, please fax them to 1.888.242.6230.

**Cyramza Co-pay Program**
With the Lilly PatientOne Co-pay Program for Cyramza (cyramzahcp.com/resources/co-pay-program.html), eligible patients can lower out-of-pocket costs to pay no more than $50 per dose. (NOTE:
Financial assistance is limited to direct costs of Cyramza and does not cover any additional costs, including but not limited to fees related to the administration of Cyramza.) Eligibility criteria:

- Age 18 years or older
- Resident of the United States or Puerto Rico
- Patients must be treated with Cyramza for an FDA-approved indication
- Commercially insured patients including patients enrolled in Health Insurance Exchange Plans
- Meet income cap criteria (program is restricted to those patients whose gross household income does not exceed the greater of $100,000 or 500% of the Federal Poverty Level).

Non-eligible:

- Participants in Medicaid, Medicare, Medicare Part D, Medigap, CAHMPUS, DoD, VA, TRICARE, or any state patient or pharmaceutical assistance program
- Patients currently eligible for, or enrolled in, a Lilly patient assistance program or another co-pay assistance program for Cyramza
- Patients, pharmacists, and prescribers cannot seek reimbursement from health insurance or any third party for any part of the benefit received by the patient through this offer.

Maximum patient benefit: $42,000 per 12-month period. Patients who continue Cyramza treatment and wish to participate in the Cyramza Co-pay Program must re-enroll every 12 months.

Patient Enrollment Steps:

1. Download an application form: lillypatientone.com/assets/pdf/patient_assistance_program_application.pdf or call Patient One at 1.866.4PatOne (1.866.472.8663) for a faxed copy.
2. Review program eligibility with your patient based upon the full criteria listed in the application.
3. Fax the completed application to 1.877.366.0585, and remind the patient to provide all required documentation. Proof of income required. Possible documents to prove income: copy of W-2; or copy of prior year tax return; or copy of most recent pay stub; or copy of social security check or awards letter.
4. Your patient’s application will be reviewed to determine eligibility pursuant to business rules.
5. Approved patients will receive an enrollment letter and their co-pay card in the mail.
6. Your office will be informed of patient’s enrollment status through a faxed letter. (NOTE: remind patients to bring their co-pay card with them to their next appointment.)

Questions? Call 1.866.4PatOne (1.866.472.8663).

REIMBURSEMENT ASSISTANCE

Lilly PatientOne Reimbursement Services

PatientOne offers resources that may help your qualified uninsured, underinsured, and insured patients obtain financial and reimbursement assistance including:

Insurance Expertise
- Coding and billing information
- Payment methodologies and allowables
- Payer policy information.

Reimbursement Assistance
- Eligibility determination
- Benefits investigation
- Prior authorization
- Evaluation other funding options.

Denied Claim Appeals
- Appeals status if requested
- Denied claims appeals templates, forms, and checklists.

PatientOne program specialists are available Monday through Friday, 9:00 am to 7:00 pm EST. Call 1.866.4PatOne (1.866.472.8663). Learn more at: lillypatientone.com.
Oncology-related products: Emend® (aprepitant), Emend® (fosaprepitant dimeglumine) for Injection, Intron® A (interferon alfa-2b, recombinant) for Injection, Keytruda® (pembrolizumab) for injection, for intravenous use, Sylatron™ (peginterferon alfa-2b) for Injection, Temodar® (temozolomide) available as capsules or for injection, Zolinza® (vorinostat)

Vaccine: Gardasil [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], Gardasil®9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

PATIENT ASSISTANCE
Merck Access Program
The Merck Access Program (merckaccessprogram.com) can help answer questions about access and support, including:
- Insurance coverage for patients
- Reimbursement
- Co-pay assistance for eligible patients
- Benefit investigations, prior authorizations, and appeals
- Referrals to the Merck Patient Assistance Program.

A dedicated representative of the Merck Access Program may be able to:
- Research your patient’s insurance benefits
- Obtain information on your patient’s out-of-pocket costs
- Provide information on co-pay assistance options
- Refer patients to the Merck Patient Assistance Program
- Answer questions about filling out the enrollment form.

Contact the Merck Access Program at 855.257.3932, Monday through Friday, 8:00 am to 8:00 pm EST. Or download the enrollment form at: merckaccessprogram.com/static/pdf/ONCO-1143560-0002.pdf and fax it to: 855.755.0518.

The Merck Patient Assistance Program
This program (merckhelps.com) provides certain Merck medicines and vaccines free of charge to eligible individuals, primarily the uninsured, who without assistance could not afford these needed Merck medicines. The Merck Access Program was designed to help patients who have been prescribed any of the following Merck medicines:
- Emend (aprepitant) 80 mg, 125 mg capsules
- Emend (fosaprepitant dimeglumine) for Injection 150 mg
- Intron A (interferon alfa-2b, recombinant) for Injection, 10 million IU, 18 million IU, 50 million IU
- Keytruda (pembrolizumab) Injection [liquid formulation] 100 mg
- Sylatron (peginterferon alfa-2b) for injection, for subcutaneous use, 200 mcg, 300 mcg, 600 mcg
- Temodar (temozolomide) Capsules 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg
- Zolinza (vorinostat) 100 mg Capsules.

The Merck Patient Assistance Program offers temporary assistance to patients who generally meet the following requirements:
1. They are a U.S. resident and physician/prescriber has determined that a Merck product may be appropriate for treating the patient
2. They have no pharmaceutical insurance coverage
3. They meet specified financial criteria and cannot afford to pay for their medicine.

NOTE: Individuals who do not meet the insurance criteria may still qualify for the Merck Patient Assistance Program if they attest that they have special circumstances of financial and medical hardship, and their income meets the program criteria.

To enroll in the Merck Patient Assistance program, visit merckhelps.com. This site will refer you to the Merck Access site for the specific medication you are prescribing, and it is where patients can begin the enrollment process, using the prescription specific enrollment form. Questions about the Merck Patient Assistance Program? Call 1.800.727.5400, Monday through Friday, 8:00 am to 8:00 pm EST.

Co-Pay Assistance for Keytruda
The Merck Co-Pay Assistance Program offers assistance to eligible patients who need help affording Keytruda. Co-pay assistance may be available for patients who:
• Are at least 18 years of age
• Are a resident of the U.S. (including Puerto Rico)
• Have private health insurance that covers Keytruda under a medical benefit program
• Have been prescribed Keytruda for an FDA-approved indication

• Meet financial eligibility criteria (To view the criteria visit: merckaccessprogram-keytruda.com/hcp/the-merck-copay-assistance-program/ and select the link for “Terms and Conditions”)• Meet all other terms and conditions as outlined on the Keytruda co-pay assistance website

Once enrolled, eligible, privately insured patients pay the first $25 of their co-pay per infusion. The maximum benefit under this program is $25,000 per patient per calendar year (based on income).

Download the Merck enrollment form at: merckaccessprogram-keytruda.com/static/pdf/merck-access-program-keytruda-enrollment-form.pdf and fax it to: 855.755.0518 or enroll online at: merckaccessprogram-keytruda.com/hcp/merck-access-program-keytruda-enrollment-form/.

NOTE: Co-pay assistance from the Merck Co-pay Assistance Program is not insurance. Visit the Merck Co-pay Assistance Program website (link above) for restrictions, terms, and conditions. If your patient is deemed ineligible for the Merck Co-pay Assistance Program for Keytruda, a representative can provide you with information about independent foundations that may be able to provide your patient with financial support. Each independent foundation has its own eligibility criteria and application process.

Vaccine Patient Assistance Program
Patients who want to receive the Gardasil vaccine may be eligible for the program if all three of the following conditions apply:
• Patients reside in the U.S. and are 19 to 26 years of age. (NOTE: Patients do not have to be U.S. citizens. Legal residents of the U.S. and U.S. territories are also eligible to apply.)
• Patients have no health insurance coverage. (Some examples of health insurance coverage include private insurance, HMOs, PPOs, college health plans, Medicaid, veterans’ assistance, or any other social service agency support.)
• Patients have an annual household income less than:
  - $47,520 or less for individuals
  - $64,080 or less for couples
  - $97,200 or less for a family of 4.

For income limits in Alaska and Hawaii, please call 1.800.727.5400.

NOTE: Individuals who do not meet the insurance coverage criteria may still qualify for the vaccine program if the patient has special circumstances of financial and medical hardship, and their income meets the program criteria.
Enrollment is Easy
1. Complete and sign the application form. It is available online at: merckhelps.com/docs/VPAP_Enrollment_Form_English.pdf (English) and merckhelps.com/docs/VPAP_Enrollment_Form_Spanish.pdf (Spanish). Providers and their office personnel can also call 1.800.293.3881, Monday through Friday, 8 am to 8 pm EST, to obtain enrollment applications for patients and to request additional information about the program.

2. Fax the completed form to: 1.800.528.2551 from a participating licensed provider’s office. The application must be submitted and approved prior to administration of vaccine in order to qualify. Forms will be processed quickly—with a goal of less than 10 minutes (between business hours of 8:00 am-8:00 pm, EST, Monday through Friday)—and the provider’s office will be notified by phone so that qualifying patients can receive the Merck vaccine during that visit.

3. A new application will need to be completed and submitted to the Merck Vaccine Patient Assistance Program for eligibility assessment prior to a patient receiving a subsequent dose in a multidose series or for another Merck vaccine.

2016 Federal Poverty Guidelines

<table>
<thead>
<tr>
<th>Family Size</th>
<th>100%</th>
<th>133%</th>
<th>138%</th>
<th>250%</th>
<th>400%</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>$11,770</td>
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<td>$26,719</td>
<td>$27,724</td>
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<td>4</td>
<td>$24,250</td>
<td>$32,252</td>
<td>$33,465</td>
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<td>5</td>
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<td>6</td>
<td>$32,570</td>
<td>$43,318</td>
<td>$44,946</td>
<td>$81,425</td>
<td>$130,280</td>
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<td>7</td>
<td>$36,730</td>
<td>$48,850</td>
<td>$50,687</td>
<td>$91,825</td>
<td>$146,920</td>
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<td>8</td>
<td>$40,890</td>
<td>$54,383</td>
<td>$56,428</td>
<td>$102,225</td>
<td>$160,360</td>
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</tbody>
</table>
PATIENT ASSISTANCE

PROVYDE™ (ONIVYDE ACCESS SERVICES)

PROVYDE offers the following patient assistance services:

- $0 commercial co-pay program
- Patient assistance program
- Referrals to independent, non-profit organizations for state or federally-insured patients
- Referrals for transportation assistance.

Co-Pay Assistance

PROVYDE’s $0 Commercial Co-pay Program assists eligible commercially-insured patients with their out-of-pocket prescription costs. To be eligible for this program, patients must:

- Receive treatment in the U.S. or U.S. territory
- Be commercially-insured
- Be prescribed Onivyde for an FDA-approved indication
- Have an annual income of 400% of the federal poverty level and documentation, such as the most recent U.S. income tax return, most recent pay stub, or most recent Social Security income statement, or a notarized letter stating patient has no annual income
- Not be enrolled in any federal, state, or government-funded healthcare program, such as Medicare, Medicaid, VA, DoD, or TriCare.

Patient Assistance Program

To be eligible for this program, uninsured and functionally uninsured patients must:

- Receive treatment in the U.S. or U.S. territory
- Be uninsured or functionally uninsured (“functionally uninsured” patients are patients that are enrolled in a healthcare plan that does not cover treatment with Onivyde)
- Be prescribed Onivyde for an FDA-approved indication
- Have an annual income of 400% of the federal poverty level and documentation, such as the most recent U.S. income tax return, most recent pay stub, or most recent Social Security income statement, or a notarized letter stating patient has no annual income
- Not be enrolled in any federal, state, or government-funded healthcare program, such as Medicare, Medicaid, VA, DoD, or TriCare.

Enrollment

Patients can enroll online at: onivyde.com/_assets/pdf/PROVYDE_Start_Form.pdf. For insurance verification, referral to an independent, non-profit organization, and/or referral for travel assistance, complete page 2 only (sections 1, 2, 3, and 4). To enroll in the $0 Commercial Co-pay Program or the Patient Assistance Program, complete pages 2 and 3 (sections 1, 2, 3, 4, 5, and 6). (Note: Page one of the application contains instructions for filling out the application, and does not need to be completed. Although only page 2 is required for referral to an independent, non-profit organization, completion of page 3 of the application may help expedite the application process for non-profit assistance.) Print and fax completed forms to: 844.269.3039. Or mail completed form to: PROVYDE Access Services, PO Box 4133, Gaithersburg, MD 20885-4133.
PROVYDE Access Services will acknowledge receipt of the form, initiate the services requested, and relay all results to the provider’s office. Applications are determined on a case-by-case basis.

**REIMBURSEMENT ASSISTANCE**

**PROVYDE**

PROVYDE offers the following reimbursement services: benefit verifications, prior authorization support, and claims and appeals support. For more information call 844.ONIVYDE (664.8933), Monday through Friday, 8:00 am to 8:00 PM EST or go online to: https://www.onivyde.com onivyde-access-services/.
Novartis Pharmaceuticals Corporation

Oncology-related products: Afinitor® (everolimus) tablets, Arzerra® (ofatumumab) injection, Exjade® (deferasirox) tablets for oral suspension, Farydak® (panobinostat) capsules, Femara® (letrozole) tablets, Gleevec® (imatinib mesylate) tablets, Jadenu™ (deferasirox) tablets, Mekinist® (trametinib) tablets, Odomzo® (sonidegib), Promacta® (eltrombopag) tablets, Sandostatin® (octreotide acetate) for injection, Sandostatin LAR® Depot (octreotide acetate for injectable suspension), Tafinlar® (dabrafenib) capsules, Tasigna® (nilotinib) tablets, Tykerb® (lapatinib) tablets, and Votrient® (pazopanib) tablets, Zykadia™ (ceritinib) capsules

Patient and Reimbursement Assistance Websites
hcp.novartis.com/access
patientassistanecnov.com

PATIENT ASSISTANCE

The Novartis Patient Assistance Foundation

This foundation (patientassistance now.com/info/programsto accessmedicines/patientassistance information.jsp) provides assistance to patients experiencing financial hardship who have no third-party insurance coverage for their medicines. To be eligible for the Novartis Patient Assistance Fund, patients must:
- Be a U.S. resident.
- Meet income criteria, which vary by medication, and provide proof of income. Financial eligibility program requirements are 250% to 500% of the Federal Poverty Level, depending on the Novartis medicine. (See income chart below.)
- Not have private or public prescription coverage. (NOTE: Exception process exists.)

Table 1. Novartis Patient Assistance Foundation: Total Yearly Income Range

<table>
<thead>
<tr>
<th>Household Size</th>
<th>250% Federal Poverty Level</th>
<th>300% Federal Poverty Level</th>
<th>500% Federal Poverty Level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>General medicines and primary care medicines</td>
<td>Transplant, antipsychotics, cystic fibrosis, hepatitis B</td>
<td>Oncology and multiple sclerosis</td>
</tr>
<tr>
<td>1 Person</td>
<td>$29,175</td>
<td>$35,010</td>
<td>$58,350</td>
</tr>
<tr>
<td>2 Person</td>
<td>$39,325</td>
<td>$47,190</td>
<td>$78,650</td>
</tr>
<tr>
<td>4 Person</td>
<td>$59,625</td>
<td>$71,550</td>
<td>$119,250</td>
</tr>
</tbody>
</table>
Patients must reapply and re-qualify every 12 months. Questions? Contact the Novartis Patient Assistance Foundation at: 1.800.277.2254, or go online to: patientassistancenow.com.

There are three ways to enroll in the program:
- Enroll online by visiting: pharma.us.novartis.com/info/patient-assistance/patient-assistance-enrollment.jsp, and selecting the appropriate Novartis medication from the drop down menu, and following the instructions
- Call 1.800.277.2254 to enroll by phone. (Note: If you have prescribed Exjade [deferasirox] tablets to your patient, call the EPASS Prescription and Reimbursement Hotline at 1.888.903.7277.)

Novartis Oncology Universal Co-Pay Card
Novartis Oncology created its Universal Co-Pay Program (copay.novartisoncology.com) to help with prescription costs for all the medications listed below:
- Afinitor
- Exjade
- Farydak
- Femara
- Gleevec
- Jadenu
- Mekinist
- Odomzo
- Promacta
- Sandostatin LAR Depot
- Tafinlar
- Tasigna
- Tykerb
- Votrient
- Zykadia

It’s simple to use and easy to find out if patients are eligible for the program. Eligible patients may pay no more than $25, subject to a maximum benefit of $15,000 per calendar year. Find out if this program is right for your patient by calling 1.877.577.7756 or by going to: copay.novartisoncology.com and clicking on the name of the medication. This offer is not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this program without notice. Limitations apply. Read program terms and conditions at: copay.novartisoncology.com.

Patient Assistance NOW Oncology (PANO)
PANO (oncologyaccessnow.com) offers quick and easy access to information about the wide range of resources available to your patients. Enroll your patients into Novartis Oncology support programs by completing this form: hcp.novartis.com/globalassets/approved-onc-1112163-novartis-universal-enrollment-form-gsk-update-digital1.pdf.

Follow the steps below to complete the Novartis Service Request Form:
- Patient Information (Section 1). Complete with all relevant information. Be sure to have the patient sign the Patient Authorization and the Patient Assistance Program (PAP) Consent for Patient (if applicable). For Zykadia and Farydak specialty pharmacy submission only, patient signature is not mandatory.
- Insurance Information (Section 2). Please include a copy of the front and back of the patient’s insurance card(s).
- Patient Financial Information (Section 3). This section only needs to be completed if you believe the patient could be eligible for the Patient Assistance Program (PAP). For patient assistance consideration, please attach proof of income, i.e., wage stubs, employer statement of income, tax returns, etc.
- Physician Information (Section 4). Complete with all relevant information and best contact person. Be sure to sign the Physician Authorization and Patient Assistance Program (PAP) Consent for Physician (if applicable).
- Pharmacy Preference (Section 5). Choose your patient’s preferred pharmacy (if applicable).
- Prescription Information (Section 6). Please complete the selected prescription information for your patient. Ensure that all necessary prescriber signatures are included.

Fax completed forms to: 1.888.891.4924. (NOTE: follow instructions on enrollment form for enrolling patients on Zykadia and Farydak through a specialty pharmacy.) Questions? Call 1.800.282.7630, Monday through Friday, 9:00 am to 8:00 pm EST.
REIMBURSEMENT ASSISTANCE

Patient Assistance NOW Oncology (PANO)
PANO (oncologyaccessnow.com) helps patients and healthcare providers with questions about insurance verification and other reimbursement issues including,
- Benefits investigations
- Prior authorizations
- Assistance with denials and appeals.

Providers can download and complete the Novartis Service Request Form at: hcp.novartis.com/globalassets/approved_onc-1112163-novartis-universal-enrollment-form-gsk-update-digital1.pdf and, following the directions above, fax it to: 1.888.891.4924 (NOTE: follow instructions on enrollment form for enrolling patients on Zykadia and Farydak through a specialty pharmacy.) Questions? Call 1.800.282.7630.

Oncology Reimbursement Hotline
By calling 1.800.282.7630, providers and patients can receive assistance in resolving reimbursement issues and concerns, including:
- Insurance verification. Program staff verify patients’ medical benefits, helps determine insurance coverage, and clarify co-payment obligations.
- Denials and appeals. Program staff can assist you and your patient with the appeals process.
- Referrals to co-pay cards.
- Alternative funding searches. Program staff can search for possible assistance for patients with insufficient medical benefit coverage or no drug coverage and refer to other sources of funding that could help alleviate or reduce costs.
- Referrals to patient assistance for low-income uninsured patients.
- Help finding pharmacies that stock Novartis medication. Program staff can also overnight an emergency supply, and find other ways to get your patient their Novartis medicine.

The Reimbursement Hotline and Novartis Pharmaceuticals Corporation do not guarantee success in obtaining reimbursement, nor do they submit appeals on behalf of providers or patients. Third-party payment for medical products and services is affected by numerous factors, not all of which can be anticipated or resolved by Reimbursement Hotline staff.
Pfizer, Inc.

Oncology-related products: Aromasin® (exemestane tablets), Bosulif® (bosutinib) tablets, Camptosar® (irinotecan HCl injection), Ellence® (epirubicin hydrochloride injection), Emcyt® (estramustine phosphate sodium capsules, Ibrance® (palbociclib), Idamycin® (idarubicin hydrochloride for injection, USP), Inlyta® (axitinib) tablets, Neumega® (oprelvekin), Sutent® (sunitinib malate), Torisel® (temsirolimus) injection, Xalkori® (crizotinib) capsules, Zinecard® (dexrazoxane for injection)

Patient and Reimbursement Assistance Website
pfizerrxpathways.com

PATIENT ASSISTANCE

Pfizer RxPathways
For more than 25 years, Pfizer has offered a number of assistance programs to help eligible patients access their prescription medicines. Now, to answer patients’ changing needs and make our services more accessible, we’ve combined our existing programs into one program called Pfizer RxPathways. Formerly Pfizer Helpful Answers, Pfizer RxPathways is a comprehensive assistance program that provides eligible patients with a range of support services, including insurance counseling, co-pay assistance, and access to medicines for free or at a savings.

Services for Uninsured Patients
Uninsured patients may be able to get certain specialty medicines for free if they cannot secure insurance coverage. To apply for free medicine, patients and their prescribers must download and complete the Group B application at: pfizerrxpathways.com/sites/default/files/attachment/PRxP_Application_Group_B_English_4.20.15_1.pdf. The application, along with any other required documents should be faxed to: 800.708.3430 or mailed to: Pfizer RxPathways, P.O. Box 66976, St. Louis, MO 63166-6976.

If patients require immediate assistance with their specialty medicines, they or their prescribers should call 1.877.744.5675, Monday through Friday, 8:00 am to 8:00 pm.

To be eligible for free specialty medicines, uninsured patients must:
• Be prescribed a Pfizer specialty, or “Group B,” medicine. To view these medicines, click “View Group B Medicine List” on the Pfizer RxPathways website (http://pfizerrxpathways.com/en/see-how-we-help).
• Have no prescription coverage to pay for their Pfizer medicines.
• Meet certain income limits that vary by medicine and household size.
• Live in the United States, Puerto Rico, or the U.S. Virgin Islands.
• Be treated as an outpatient.

After applying or contacting Pfizer RxPathways, a Pfizer RxPathways counselor will first work with uninsured patients to find and apply for insurance options that may help them access their Pfizer specialty medicines (e.g., state pharmaceutical assistance programs, Medicaid, Medicare Part D, and low-income subsidies). During this time, eligible patients will be given up to a 90-day supply of free medicine. If eligible patients cannot secure insurance coverage, they will continue to get free medicine through Pfizer RxPathways for up to 12 months.
Within two business days, patients will be notified of their enrollment status over the phone. If accepted, patients will then receive a letter containing their enrollment term and next steps on how to receive their free specialty medicine(s). For more information on the eligibility requirements, application, and enrollment process, see the Group B application: pfizerrxpathways.com/sites/default/files/attachment/PRxP_Application_Group_B_English_4.20.15_1.pdf.

Services for Underinsured Patients
If patients have prescription coverage, but still cannot afford their Pfizer specialty medicines, they may be able to get them for free. To be eligible for free specialty medicines, patients without enough health insurance coverage must:
• Be prescribed a Pfizer specialty, or “Group B,” medicine. To view these medicines, click “View Group B Medicine List” on the Pfizer RxPathways website (http://pfizerrxpathways.com/en/see-how-we-help).
• Have prescription coverage, but not enough to pay for their Pfizer medicines
• Meet certain income limits that vary by medicine and household size
• Live in the United States, Puerto Rico, or the U.S. Virgin Islands
• Be treated as an outpatient.

To apply for free medicine, patients and their prescribers must download and complete the Group B application (pfizerrxpathways.com/sites/default/files/attachment/PRxP_Application_Group_B_English_4.20.15_1.pdf) and mail or fax it (see address and fax number above) to Pfizer RxPathways along with any other required documents. If patients require immediate assistance with their specialty medicines, they or their prescribers should call 1.877.744.5675, Monday through Friday, from 8:00 am to 8:00 pm EST to start the process.

After applying to or contacting Pfizer RxPathways, a Pfizer RxPathways counselor will first work with underinsured patients to find and apply for other ways to help patients with their co-pay. Other sources of help could come from co-pay foundations, Medicare Part D, low-income subsidies, and even co-pay card programs. If other funding cannot be secured, patients may be eligible to receive their Pfizer specialty medicines for free through Pfizer RxPathways.

Within two business days, patients will be notified of their enrollment status. If accepted, they will receive a letter that contains their enrollment term and next steps on how to receive their free specialty medicine(s). Medicines will typically be shipped to a patient’s home, or to a prescriber’s office.

In some cases, patients who apply for free medicine and have private insurance coverage may instead receive co-pay assistance through Pfizer RxPathways. Instead of having free medicine shipped to them, these patients will receive a Pfizer RxPathways co-pay card to use at their local pharmacy to cover the entire cost of their co-pay.

My Pfizer Brands
My Pfizer Brands is a program that helps patients receive prescription savings on the Pfizer medications they have been prescribed. Many people, even those with prescription coverage, may save with this program. Terms and conditions apply. If the product is available as a generic, patients may pay less with other offers or by receiving the generic. See full terms and conditions on each respective Pfizer brand medication website. Card will be accepted only at participating pharmacies. Card is not health insurance. No membership fees. Maximum annual savings of $400 to $10,000. For more information, call 1.866.341.9100 or write to Pfizer, PO Box 29387, Mission, KS 66201-9618.

Regardless of income or employment status, patients may qualify for the My Pfizer Brands program if:
• They pay for prescriptions with insurance at the pharmacy (this...
means they are self-insured or have prescription coverage through their employer or their spouse’s employer
- They pay out-of-pocket (cash) for their prescriptions at the pharmacy
- They do not purchase prescriptions through Medicare, Medicaid, or a federal or state program
- They are not a resident of a state where this program is prohibited by law. (Please check your brand’s website for specific terms and conditions.)

To verify eligibility, select brand-name product from those listed in the keyboard located on the My Pfizer Brands home page (mpfizerbrands.com) then click through to the available savings offer. If patients are not eligible, there may be other ways they can save on their prescriptions through Pfizer RxPathways, Pfizer’s patient assistance program. Learn more at: PfizerRxPathways.com.

REIMBURSEMENT ASSISTANCE

Insurance Counseling
If insured or underinsured patients need help understanding their coverage and reimbursement options for certain Pfizer specialty medicines, Pfizer RxPathways can help by offering:
- **Reimbursement support.** A Pfizer RxPathways counselor will research and verify benefits, outline coverage options and policies, and explain the prior authorization process to patients and their prescribers.
- **Appeals process information.** If a claim is underpaid or denied, Pfizer RxPathways will investigate it and provide patients with information on the appeals process.
- **Specialty pharmacy referral.** For patients prescribed Bosulif, Ibrance, Inlyta, Sutent, or Xalkori (crizotinib), Pfizer RxPathways will refer them to a retail or specialty pharmacy that will verify their benefits and help to fill their prescriptions.

To receive insurance counseling for certain specialty medicines, patients can call 1.877.744.5675, Monday through Friday, 8:00 am to 8:00 pm EST. Patients can also download and submit the Group B application to begin the process. For more information on the eligibility requirements, application, and enrollment process, see the Group B application: pfizerrxpathways.com/sites/default/files/attachment/PRxP_Application_Group_B_English_4.20.15_1.pdf.

Pfizerpro.com
PfizerPro (pfizerpro.com) offers physicians the support they need to help improve their practice and the lives of their patients, including:
- **Clinical trial listings.** Search the database of ClinicalTrials.gov for available clinical trials by keyword, trial phase, location, and more.
- **Digital product presentations.** These self-guided, online learning sessions are available for certain Pfizer products and are designed to leave providers with a clearer understanding of the Pfizer product discussed.

The presentations feature case studies, mechanism of action videos, efficacy and safety information, and more, all of which can be viewed at your own pace from either your desktop or tablet device.
- **Grants and fellowships.** Pfizer seeks to cooperate with healthcare delivery organizations and professional associations to narrow professional practice gaps in areas of mutual interests through support of learning and change strategies that result in measurable improvement in competence, performance, or patient outcomes.
- **Hispanic/Latino learning series** are PowerPoint presentations designed to educate healthcare professionals and other key stakeholders on cultural competency for Hispanic/Latino populations.
- **Pfizer medical information.** Have a medical question? Submit a medical question, chat live about Pfizer prescription medicines, and more.
- **Pfizer patient-reported outcomes** is a resource for up-to-date versions and translations of many available measures used to assess patient-reported outcomes. It offers current information on validated measures developed by Pfizer in various therapeutic areas, including CV/metabolic, neuroscience, oncology, pain, sexual health, urology, and women’s health.
- **Pfizer Responsible Disposal Advisor** assists institutional facilities in properly disposing...
of unused medicine. The site is now available to healthcare facilities and providers. Answers to your product disposal questions are only a click away.

- Pfizer samples. Eligible healthcare professionals can sign in or register for PfizerPro, choose from eligible samples or savings cards, and submit their requests. PfizerPro members can also call 1.888.736.8220 for more information and to request samples. (NOTE: Not all Pfizer products are available for sampling through this program.)

- Vaccine ordering. Pfizer is committed to the prevention of life-threatening diseases. For over a century, Pfizer and its legacy companies have played a critical role in technological developments against diseases such as pneumococcal pneumonia. This is where you can order vaccines for your practice.

### Benefit Verification & Prior Authorization Checklist

**Does the patient’s insurance plan provide coverage for the drug under a medical benefit or pharmacy benefit?**

☑ Does the patient’s insurance plan require prior authorization for the drug before initiation of therapy?

- What information does the patient’s insurance plan need for the prior authorization process?
- Typically, how long will the prior authorization process take?
- Once obtained, how long will the prior authorization last before another one is required?
- What are the patient’s cost-sharing responsibilities?
- What is the patient’s annual deductible? If the deductible has not yet been met in full, how much is left?
- What is the patient’s maximum out-of-pocket requirement? If the maximum out-of-pocket has not yet been met in full, how much is left?

☑ Does the patient have other non-primary sources of healthcare coverage, which need coordination of benefits with the primary source?

☑ Does the patient’s insurance plan have any coding or claims submission guidelines which must be followed for reporting the drug and its administration?

☑ How much reimbursement does the patient’s insurance plan provide for the drug and its administration within the physician office setting?

☑ How much reimbursement does the patient’s insurance plan provide for the drug and its administration within the hospital outpatient setting?

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Source: The ACCC Financial Advocacy Network. accc-cancer.org/FAN.
Oncology-related products: Imbruvica™ (ibrutinib)

Patient and Reimbursement Assistance Website
imbruvica.com/youandi

PATIENT ASSISTANCE

YOU&i Access™ Instant Savings Program

Patients with commercial insurance and who meet eligibility requirements will pay no more than $10 per month for Imbruvica. (NOTE: Month refers to a 30-day supply. Subject to a maximum benefit, 12 months after activation or 12 monthly fills [one-year supply]. This program is not valid for patients enrolled in Medicare, Medicaid, or other state or federal healthcare programs. For these patients, foundation support may be available.) The program can also provide information on independent foundations that may be able to provide patients with additional financial support. (NOTE: The Johnson & Johnson Patient Assistance Foundation, Inc. may be able to help uninsured individuals who are unable to pay for their Imbruvica medication. Contact a JJPAF program specialist at 1.800.652.6227 from 9:00 am to 6:00 pm EST, or visit the foundation website at jjpaf.org to see if your patient might qualify for assistance.

YOU&i™ Start Program

For patients experiencing coverage decision delays the YOU&i™ Start Program may be able to provide access to Imbruvica. Eligible new patients who have been prescribed Imbruvica for an FDA-approved indication, and who are experiencing an insurance coverage delay greater than five business days, can receive a free, 30-day supply of the drug. If the decision delay persists, an additional free, 30-day supply may be provided. The free product is offered to eligible patients without any purchase contingency or other obligation.

REIMBURSEMENT ASSISTANCE

Imbruvica YOU&i™ Support Program

This personalized support program from Pharmacycics, Inc., and Janssen Biotech, Inc., includes information on access and affordability, nurse call support, and resources for patients being treated with Imbruvica. Healthcare providers can help enroll patients in this program before they start taking Imbruvica. For more information, call 1.877.877.3536, Monday through Friday, 8:00 am to 8:00 pm EST. Enroll online at: imbruvica.com/reg or download the enrollment form at: imbruvica.com/docs/librariesprovider3/default-document-library/enrollment_form.pdf?sfvrsn=6. The Imbruvica YOU&i Support Program provides:

- Rapid (2 business days) benefits investigation
- Information about the prior authorization process
- Information about the insurance appeals process
- Help connecting to a specialty pharmacy (List of specialty pharmacies can be found here: imbruvica.com/docs/librariesprovider3/default-document-library/specialty_pharmacies.pdf?sfvrsn=8).

Nurse Call & Support Resources

In addition to the services outlined above, the Imbruvica patients can have ongoing tips, tools, and other resources sent via email or to their home address. New Imbruvica patients will also receive a Patient Starter Kit.
PATIENT ASSISTANCE

Sandoz One Source™

Sandoz One Source is a comprehensive program designed to help simplify and support patient access for those prescribed Zarxio. Sandoz One Source offers a variety of customized services for patients, including:

• Comprehensive insurance verifications
• Prior authorization support, when required by the insurance company
• Billing and coding information
• Claims tracking information
• Denials/Appeals information
• General payer policy research.

Sandoz One Source is available to assist patients with:

• Information on external resources and support
• Sandoz One Source Commercial Co-Pay Program eligibility.

Download an enrollment form for patient assistance at: sandozonesource.com. For patient assistance program, complete Sections 1-6, and Section 8. For reimbursement assistance, enrollment in the Sandoz One Source Co-pay Program, and/or information on external resources, complete sections 1-7:

Section 1: Patient information

Section 2: Insurance information. Include policy information for both your patient’s primary and secondary insurance (as applicable). It helps to include a copy of the front and back of the patient’s insurance card(s). If your patient has no insurance, check the “No Insurance” box.

Section 3: Treatment & prescribing information. Primary and secondary ICD/Dx are required. Remember to enter Drug name in the first row of this section.

Section 4: Prescriber information. Include office/primary contact person.

Section 5: Patient authorization & signature.

Section 6: Prescriber authorization.

Section 7: Commercial co-pay program. Skip this section if applying for the patient assistance program.

Section 8: Patient consent/signature & financial information. Complete only if you believe the patient could be eligible for patient assistance. For patient assistance consideration, patients may sign consent for real-time income projector or may opt to include proof of income documentation. The enrollment form is also available online via the Sandoz One Source Provider Portal. To access the Provider Portal visit: sandozonesource.com. Questions? Call 844.SANDOZ1 (844.726.3691), 9:00 am to 8:00 pm EST, Monday through Friday.

SANDOZ ONE SOURCE CO-PAY PROGRAM

The Sandoz One Source Co-pay Program is available for all eligible, commercially insured patients who have been prescribed Zarxio. There is no income eligibility requirement for this program. Under this program, patients pay $0 for their

Sandoz, Inc.

Oncology-related product: Zarxio™ (filgrastim-sndz)
first dose or cycle, and are responsible for a $10 out-of-pocket cost for subsequent doses or cycles, subject to a maximum benefit of $10,000 annually.

The Sandoz One Source Co-pay Program is not insurance. It is available only to patients with commercial insurance. Cash-paying patients, uninsured patients, and patients with federal or state-funded insurance are not eligible for this program. The program not available in states where it is prohibited by law. Patients must be prescribed Zarxio for an FDA-approved indication. Patients can participate in the program for up to 12 months or until age 65, whichever comes first. Other terms and conditions apply.

To enroll in the Sandoz One Source Co-pay Program patients must complete the Sandoz One Source enrollment form described above. Patients should complete Sections 1-7 of the form. To enroll, or to learn more about the program restrictions and eligibility requirements visit: www.sandozonesource.com, or call: 844.SANDOZ1 (844.726.3691), 9:00 am to 8:00 pm EST, Monday through Friday.

**REIMBURSEMENT ASSISTANCE**

Sandoz One Source offers a variety of reimbursement assistance services for patients and providers. For reimbursement assistance, complete the Sandoz One Source enrollment form, Sections 1-7, found at: www.sandozonesource.com. Reimbursement services include:

- Comprehensive insurance verifications
- Prior authorization support, when required by the insurance company
- Billing and coding information
- Claims tracking information
- Denials/Appeals information
- General payer policy research.

You can download the enrollment form, or enroll your patients online via the Sandoz One Source Provider Portal. Questions? Call 844.SANDOZ1 (844.726.3691), 9:00 am to 8:00 pm EST, Monday through Friday.
Oncology-related products: Elitek® (rasburicase), Eloxatin® (oxaliplatin injection), Jevtana® (cabazitaxel), Leukine® (sargramostim), Mozobil® (plerixafor injection), Taxotere® (docetaxel injection), Thymoglobulin® (anti-thymocyte globulin [rabbit]), Zaltrap® (ziv-aflibercept) a collaboration between Sanofi and Regeneron Pharmaceuticals, Inc.

**PATIENT ASSISTANCE**

**Sanofi Patient Connection™**

This program can provide medication at no cost if patients meet program eligibility requirements. This component of the program is made possible through the Sanofi Foundation for North America. In order to be eligible for the program, patients must meet the following requirements:

- Must be a U.S. citizen or resident and be under the care of a licensed healthcare provider authorized to prescribe, dispense and administer medicine in the U.S.
- Must have no insurance coverage or access to the prescribed product or treatment via their insurance.
- Must meet the following financial criteria: 1) Annual household income of ≤250% of the current Federal Poverty Level for all non-oncology/non-hematology products; 2) Annual household income of ≤500% of the current Federal Poverty Level for all oncology/hematology products.
- Must not be eligible for Medicare or Medicaid. (Patients who are enrolled in Medicare Part D may still be eligible for patient assistance if they meet all of these requirements and 1) are not be eligible for Low Income Subsidy, 2) do not have coverage for a generic equivalent, and 3) have out-of-pocket drug expenses of 5 percent of their household's annual income. For example, if their annual household income is $10,000, their individual out-of-pocket drug expenses would have to equal $500 or more.)

Download the application online at: sanofipatientconnection.com/media/pdf/SPC_Application.pdf.

Questions? Call 1.888.VISITSPC (1.888.847.4877), Monday through Friday, 9:00 am to 8:00 pm EST.

Completed applications can be faxed to: 1.888.847.1797 or mailed to: Sanofi Patient Connection™, PO Box 222138, Charlotte, NC 28222-2138.

**Sanofi Resource Connection**

Sanofi Patient Connection offers a unique service called Resource Connection (sanofipatientconnection.com/resource-connection) in which program counselors work with patients and providers to determine if there are alternative services available. Some examples of different types of resources and support that may be available include:

- Clinical support services
- Nutritional supplements (groceries, food banks, etc.)
- Transportation
- Health supply/cosmetic aids (wigs, scarves, etc.)
- Patient advocacy support
- Home care services support (shelters, utilities, etc.).

Download the Sanofi Patient Connection application at: sanofipatientconnection.com/media/
Sanofi Patient Connection
Sanofi Patient Connection (sanofipatientconnection.com/reimbursement-connection) can also help patients and providers determine prescription insurance coverage and options. Services include:
• Insurance verification (benefits, deductibles, co-pay, and co-insurance verification)
• Prior authorization assistance
• Coding and billing assistance
• Claims management and appeals assistance.

Download the application at: sanofipatientconnection.com/media/pdf/SPC_Application.pdf.

The Sanofi Patient Connection Provider Portal
The Sanofi Patient Connection (SPC) Provider Portal (visitspconline.com) is an efficient and convenient tool for healthcare professionals and reimbursement personnel to enroll and manage their patients into the SPC suite of patient access services. This secure, web-based provider portal is available to give access to patient case status updates, 24 hours a day, 7 days a week. If you are not already enrolled into the SPC Provider Portal, visit visitspconline.com to register. Follow these simple steps to get access:
1. Submit the registration form
2. Talk to a provider portal support team member
   • Upon receipt of your registration request, the SPC Provider Portal Support Team will contact you via phone within one to two business days to validate and confirm your registration.
3. Create a user name and password
   • Once step two is completed, you will receive an invitation email from the SPC Provider Portal Support Team. The invitation email will contain a temporary password that is valid for two weeks. Within two weeks of receiving the temporary password, log into the SPC Provider Portal (visitspconline.com), create your user name, and convert the temporary password to your own permanent password. NOTE: If you are unable to convert the temporary password to a permanent password within two weeks, you will be required to contact the SPC Provider Portal Support Team (1.888.847.4877, option 4).

Need Additional Help with the Portal? The Provider Portal Support Team is available by phone, Monday through Friday, 9:00 am to 8:00 pm ET at 1.888.847.4877, option 4. Learn more at: visitspconline.com.
Oncology-related products: Adcetris® (brentuximab vedotin)

PATIENT ASSISTANCE

SeaGen Secure ™ Patient Assistance Program
SeaGen Secure offers an Adcetris Co-insurance Assistance Program for uninsured and underinsured patients who have been prescribed Adcetris. Once an enrollment form (http://seagensecure.com/assets/pdfs/SeaGenSecure_PatientAssist-BenefitsForm_EN_NEW.pdf) has been completed, fax it to: 855.557.2480. It is important that each field is filled out completely and accurately to ensure timely processing of the application. If you have any questions, please call 855.4SEAGEN (855.473.2436), option 1, to speak with a reimbursement counselor.

Benefits Investigation
Once the enrollment form is received, a benefits investigation is conducted to determine an individual patient’s coverage for treatment. It is SeaGen Secure’s priority to make sure providers have patient-specific coverage information before starting patients on therapy with Adcetris, so they will fax providers a summary of the patient’s Adcetris-related benefits within two business days of receiving the completed request. If patient coverage for Adcetris is confirmed:

- Refer to sample claims form (seagensecure.com/assets/pdfs/Sample_CMS_1500_ADCETRIS.pdf) for billing guidance.
- If patients need help paying co-insurance, they will be assessed for eligibility for the SeaGen Secure Co-Insurance Assistance Program or referred to an independent foundation.

NOTE: To be eligible for the Co-Insurance Assistance Program, patients must have coverage for Adcetris through a commercial insurer, be at least 18 years old, and be seeking treatment for a labeled indication.

If patient does not have coverage for Adcetris:
- If the patient is insured, SeaGen Secure will assist with an appeal. If the appeal is unsuccessful, the patient will be assessed for eligibility for patient assistance.
- If the patient is uninsured, the patient will be assessed for eligibility for the SeaGen Secure Patient Assistance program.

REIMBURSEMENT ASSISTANCE
SeaGen Secure reimbursement services include:
- **Billing and coding support.** Trained reimbursement counselors provide payer-specific billing and coding requirements to assist with the billing process.
• **Prior authorization assistance.** If it is determined that Adcetris treatment requires prior authorization, SeaGen Secure can determine which forms and processes are needed to secure the authorization. Additionally, SeaGen Secure can track the prior authorization claim once it is submitted.

• **Appeal assistance and claims tracking.** If an Adcetris prior authorization or claim is denied (or partially paid), SeaGen Secure will work to determine the reason for the denial and the steps for an appeal. SeaGen Secure will also provide a sample Letter of Medical Necessity (seagensecure.com/assets/pdfs/ADCETRIS_Sample_LMN_Appeal.pdf). Medical Information may be able to assist with any additional data requests. After SeaGen Secure assists with an appeal and the documentation is submitted to the payer, they offer claims tracking to ensure the payer receives the appeal and addresses it. Claims tracking ensures that the provider is aware of claims payment and/or any payer delays in processing.

• **General payer and policy research.** Many payers have established Adcetris policies. Contact SeaGen Secure at 855.473.2436, option 1, from 9:00 am–8:00 pm EST, Monday through Friday, to inquire about a specific payer’s policy or obtain a copy of a current policy.

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**Tips for Filing Claims**

**For Electronic Claims DO...**

- Verify, file, and keep all transmission reports.
- Track clearinghouse claims to ensure successful transmission.
- Ensure your computer software is consistent with the clean claims rules.
- Verify that your software correctly prints the CMS-1500 claim form.
- Call your software vendor, if needed, to address the above two items.

**For Paper Claims DO...**

- Use only original claim forms (printed in red drop-out ink).
- Avoid folding claims, if possible.
- Resist using terms such as “refiled claim,” “second request,” or “corrected claim.”
- Avoid handwritten claims.
- Use all UPPERCASE letters.
- Stay inside the lines of each block.
- Ensure claims are printed darkly.

**For Paper Claims DON’T...**

- Use any punctuation or decimals.
- Send unnecessary attachments.
- Use staples or paperclips.
- Attach “post-it” notes.
- Mark up the claim with highlighters.
- Use circles or additional markings.
- Attach labels or stickers.
- Add notes or instructional assistance.

Source. The ACCC Financial Advocacy Network. accc-cancer.org/FAN.
PATIENT ASSISTANCE

Taiho Oncology Patient Support
Taiho Oncology Patient Support offers the following services:

- **Co-pay support** for eligible, privately insured patients. Such patients can receive a Taiho Oncology Patient Support Co-pay Card for help with out-of-pocket expenses for Lonsurf.

- **Patient Assistance Program.** Taiho Patient Support will research financial assistance options for patients with no insurance coverage, insufficient prescription coverage, or insufficient resources to pay for treatment with Lonsurf. Eligible patients may receive Lonsurf at no cost based on assistance, financial, and medical criteria.

- **Alternate funding support.** Taiho Patient Support will also refer eligible, publicly insured patients to nonprofit foundations that may be able to offer them co-pay assistance.

To enroll in Taiho Oncology Patient Support simply download the enrollment form in English at: taihopatientsupport.com/Home/ViewPef or Spanish at: taihopatient support.com/Home/ViewPefSp and fax the completed form to 1.844.287.2559. Questions? Call 844-TAIHO-4U (844.824.4648) Monday through Friday, 8:00 am to 8:00 pm EST. Or visit: taihopatientsupport.com.

REIMBURSEMENT ASSISTANCE

Taiho Oncology Patient Support
Taiho Oncology Patient Support will quickly investigate each patient’s coverage for Lonsurf and help them get access to the Lonsurf treatment they have been prescribed. Taiho Oncology Patient Support offers the following services to help improve access to Lonsurf, and to make the treatment process as simple and smooth as possible:

- **Access and reimbursement support,** including benefit investigations, assistance with prior authorizations to meet payer requirements, and claims appeals assistance if coverage is denied.

- **Specialty pharmacy prescription coordination,** including prescription triage, coordination with the in-network specialty pharmacy, self-dispensing practice, or hospital retail pharmacy, and claims appeals assistance if coverage is denied.

- **Personalized nurse support** is available for treatment plan adherence upon request. Taiho Oncology Patient Support treatment plan adherence services are available as needed to support patient care, including refill reminders.

To enroll in Taiho Oncology Patient Support simply download the enrollment form in English at: taihopatientsupport.com/Home/ViewPef or Spanish at: taihopatient support.com/Home/ViewPefSp and fax the completed form to 1.844.287.2559. Questions? Call 844-TAIHO-4U (844.824.4648) Monday through Friday, 8:00 am to 8:00 pm ET. Or visit: taihopatientsupport.com.
PATIENT ASSISTANCE

Ninlaro 1Point
This comprehensive support program offers an array of access and coverage services for patients and their healthcare providers. A dedicated case management team helps patients and providers navigate coverage requirements for Ninlaro, streamline product access, and connect to helpful resources. Services include the:

• Ninlaro Patient Assistance Program
• Ninlaro Co-Pay Assistance Program
• Ninlaro RapidStart Program.

Ninlaro Patient Assistance Program
The Ninlaro Patient Assistance Program provides free medication to eligible patients who do not have prescription drug or health insurance coverage. If patients qualify for the program, Ninlaro will be delivered to them free of charge. To apply for the Patient Assistance Program, providers must submit a completed and signed Patient Assistance Program Application and a valid prescription for Ninlaro. Patients must sign the form and submit the required household verification. If patients are approved for this program, they and their doctor will be notified and a 1-month supply of Ninlaro will be mailed to them. Each month, the provider must confirm that the patient is still being treated with Ninlaro and requires another month’s supply. Qualified patients may be enrolled for up to 1 year. Get started or to learn more by calling 1.844.N1POINT (1.844.617.6468) and selecting option 2, Monday through Friday, 8:00 am to 8:00 pm EST. Or download the enrollment form at: https://www.ninlarohcp.com/pdf/NINLARO1Point-PAP-Application.pdf and fax the completed form to: 1.844.269.3038.

Ninlaro Co-Pay Assistance Program
Eligible, commercially insured patients could pay as little as $25 per monthly prescription of Ninlaro, subject to a maximum benefit of $25,000 annually. Patients must meet eligibility requirements, however, there is no income limit for this program. This offer is valid for up to 13 prescription fills of Ninlaro per enrollment year. This savings program covers out-of-pocket expenses greater than $25 per monthly prescription. Maximum value $25,000 annually. Co-pay cards can be renewed every 12 months. This offer is not valid with any other program, discount, or incentive involving Ninlaro. This offer may be rescinded, revoked, or amended without notice. No reproductions. This offer is void where prohibited by law, taxed, or restricted. Get started or to learn more by calling 1.844.N1POINT (1.844.617.6468) and selecting option 2, Monday through Friday, 8:00 am to 8:00 pm EST. Patients can also enroll by contacting their designated specialty pharmacy. After patients are enrolled, they will receive a letter in the mail from Ninlaro 1Point, containing their co-pay card.

Ninlaro RapidStart Program
The RapidStart Program can provide a 1-cycle (the number of pills prescribed in a 28-day period)
supply of Ninlaro for patients who experience a delay in insurance coverage determination of at least 7 business days. Terms and conditions apply. Physicians must submit a completed enrollment form and a valid prescription for Ninlaro to Ninlaro 1Point on behalf of their patient. Patients must have been prescribed Ninlaro for an FDA approved indication and be new to Ninlaro therapy. Patients who have Medicare Part D or commercial insurance coverage may be eligible for this program. Get started or to learn more by calling 1.844.N1POINT (1.844.617.6468) and selecting option 2, Monday through Friday, 8:00 am to 8:00 pm EST. Or download the enrollment form at: https://www.ninlarohcp.com/1point-program and fax the completed form to: 1.844.269.3038.

The Velcade Patient Assistance Program

If patients do not have any insurance coverage, they may be eligible to participate in the Velcade Patient Assistance Program. If patients qualify for the program, Velcade will be delivered free of charge to their treating physician. Patient eligibility is based on three factors:
1. Household income
2. Treatment setting
3. Velcade prescribed for a use that is medically appropriate.

Patients who do not have insurance coverage for Velcade must apply for assistance through their healthcare professionals. To demonstrate eligibility, they must complete an enrollment form and provide income documentation, as well as health insurance information. It is strongly recommended that you enroll patients into the Patient Assistance Program prior to the start of their treatment with Velcade. All enrollment forms must be received within six months of the first treatment. The enrollment form is available online at: velcade.com/files/pdfs/VELCADE_VRAP_Enrollment_Form.pdf. You can also obtain an enrollment form by calling 1.866.VELCADE (1.866.835.2233) Monday through Friday, 8 am to 8 pm EST. Fax completed forms to: 800.891.9843. Learn more online at: velcade.com/files/PDFs/VRAP_and_Patient_Assistance.pdf or by calling 1.866.VELCADE (1.866.835.2233) and choosing option 2.

REIMBURSEMENT ASSISTANCE

Ninlaro 1Point
This comprehensive support program offers an array of access and coverage services for patients and their healthcare providers. A dedicated case management team delivers personalized services that help patients and providers navigate coverage requirements for Ninlaro, streamline product access, and connect to helpful resources. Services include:
- Benefit verification and prior authorization assistance
- Assistance with appealing a payer denial
- NINLARO Co-Pay Assistance Program enrollment for eligible, commercially insured patients
- Specialty pharmacy referral and coordination
- Referral to alternative funding sources and third-party foundations
- Connection to support services, including referrals for transportation services, legal support, and national and local organizations for counseling
- NINLARO RapidStart Program for patients with insurance-related coverage delays.

The Velcade Reimbursement Assistance Program
Dedicated (VRAP) case managers help providers and patients:
- Verify patient’s insurance coverage.
- Provide support during the appeals process in the event that a claim is denied (NOTE: VRAP case managers do not file claims or appeals on behalf of patients and cannot guarantee that patients will be successful in obtaining reimbursement).
- Identify alternate and supplemental insurance coverage options.
- Provide co-payment foundation support information.
- Screen and enroll eligible patients into the Velcade Patient Assistance Program.
- Connect patients to transportation assistance.

The enrollment form is available online at: velcade.com/files/pdfs/VELCADE_VRAP_Enrollment_Form.pdf. Fax completed forms to: 800.891.9843. Learn more online at: velcade.com/files/PDFs/VRAP_and_Patient_Assistance.pdf or by calling 1.866.VELCADE (1.866.835.2233) and choosing
option 2. Dedicated case managers are available Monday through Friday, 8:00 am to 8:00 pm EST.

**Resources for Healthcare Professionals**


Learn more at: velcade-hcp.com/reimbursement/Formslibrary.aspx.

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**Patient Assistance Checklist for Uninsured Patients**

- I have received the chemotherapy order written by the physician? □ YES □ NO
- I have met with the patient to assess his or her ability to pay for treatment?
- Based on this meeting, is the patient able to pay out-of-pocket for drug(s)? □ YES □ NO
  - If no, list drug(s) below and continue on with checklist.
- Is a replacement drug program available? □ YES □ NO
  - If yes, identify drug and program:
- Does the patient qualify for this program? □ YES □ NO
  - If no, state reason(s) why:
- If yes, I have completed all the necessary forms and paperwork for the drug replacement program. □ YES □ NO
  - If no, state reasons why:
- Does the patient need drug(s) that are not available through a drug replacement program? □ YES □ NO
  - If yes, identify which drugs:
- Is Foundation funding assistance available for any of these drug(s)? □ YES □ NO
  - If yes, identify Foundation(s) and drug(s):
- I have completed all the necessary forms and paperwork for these Foundation funding program(s). □ YES □ NO
  - If no, state reasons why:
- Does the patient qualify for charity care within from my clinic, cancer center, hospital, or healthcare system? □ YES □ NO
  - If yes, identify program:
- I have completed all the forms and paperwork necessary to apply for this charity care. □ YES □ NO
  - If no, state reasons why:
- Is there a balance or money owed related to treatment? □ YES □ NO
  - If yes, identify balance:
- If yes, I have worked with the patient and family to create a payment plan for the balance of his or her treatment costs. □ YES □ NO

**Source.** The ACCC Financial Advocacy Network. accc-cancer.org/FAN.
Tesaro, Inc.

Oncology-related supportive care product: Varubi™ (rolapitant)

Patient and Reimbursement Assistance Website
tesarobio.com/togetherwithtesaro

PATIENT ASSISTANCE

TOGETHER with TESARO™

This patient resource program is dedicated to supporting people living with cancer. The program assists with access and affordability solutions, so that patients with cancer can be free to focus on treatment goals and simply living life. It provides a full suite of services and offers each patient individualized support. A team of access and affordability experts is available to help oncology practices and patients gain access to the medication they require. In addition, Tesaro has partnered exclusively with Biologics, Inc., a trusted oncology specialty pharmacy, to provide comprehensive and personalized pharmacy care to you and your patients.

TOGETHER with TESARO offers

- Commercial co-pay assistance. (Providers must enter their NCPDP number to access the TOGETHER with TESARO Commercial Co-pay Program

Portal at: activatethecard.com/tesaro).
- Referrals to independent co-pay foundations
- A patient assistance program for eligible uninsured and underinsured patients who have a demonstrated financial hardship
- Free first dose of Varubi, if there is a delay in coverage determination.

Download the enrollment form at: tesarobio.com/pdf/US_OR_CO_09150094_TwT_Enrollment_PAP_fillable_final_110315.pdf. NOTE: Providers who wish to enroll their patients in the Together with Tesaro Patient Assistance Program must be sure to complete the third and final page of the application. Fax completed enrollment forms to: 1.800.645.9043 Questions? Call 1.844.2TESARO (1.844.283.7276), Monday through Friday, 8 am to 8 pm EST.

TOGETHER with TESARO Commercial Co-pay Assistance Program

This program may reduce out-of-pocket costs for patients with commercial insurance. The program reduces patient co-pay and/or coinsurance to $10 with a $500 annual maximum allowable benefit. Enrollment takes place through an online portal, www.activatethecard.com/tesaro. Card numbers are registered and activated upon enrollment completion. The virtual card can be initiated and utilized by pharmacies, in the office, in hospital outpatient clinics, and by Biologics, Inc., the exclusive specialty pharmacy of TESARO.

Please note: The Commercial Co-pay Assistance Program is not retroactive. It can only be applied forward from the date of enrollment for 12 months. A year following enrollment, the card expires and must be reactivated through your office.
REIMBURSEMENT ASSISTANCE

TOGETHER with TESARO Program

This patient resource program also offers assistance with:
• Insurance benefits investigation
• Prior authorizations
• Appeals

Download the enrollment form at: tesarobio.com/pdf/US_OR_CO_09150094_TwT_Enrollment_PAP_fillable_final_110315.pdf.
Fax completed enrollment forms to: 1.800.645.9043. Questions? Call 1.844.2TESARO (1.844.283.7276), Monday through Friday, 8 am to 8 pm EST.
Oncology-related therapeutic products: Bendeka™ (bendamustine hydrochloride) for Injection
Synribo® (omacetaxine mepesuccinate) for Injection; Treanda® (bendamustine HCl) for Injection,
Trisenox® (arsenic trioxide) for Injection

Oncology-related supportive care products: Actiq® (oral transmucosal fentanyl citrate) [C-II],
Fentora® (fentanyl buccal tablet) [C-II], Granix™ (tbo-filgrastim) injection

PATIENT ASSISTANCE
The Teva Cares Foundation
The Teva Cares Foundation is a conglomeration of Patient Assistance Programs designed to
improve patient access to Teva medications and ensure that cost is not a barrier to care. Through these
programs, the Teva Cares Foundation is able to provide certain Teva medications at no cost to patients in
the United States who meet certain insurance and income criteria. Eligibility is based on a patient's
income and prescription insurance status, and varies depending on the Teva medication that has
been prescribed. To determine if your patient qualifies, review the Teva Cares Foundation Patient
Assistance Programs eligibility requirements online at: tevacades.org/DoIQualify.aspx or call
877.237.4881, Monday through Friday, 9:00 am to 8:00 pm EST. Then download the appropriate
enrollment application for the Teva medication you have prescribed at: tevacades.org/DownloadApplication.aspx. Completed applications
should be faxed to the number provided at the top of the form. (NOTE: The fax number may differ depending on the Teva medication.)

If your patient does not meet the eligibility requirements for the Teva Cares Foundation Patient Assistance Programs, Teva may offer a
reimbursement assistance program or other type of program to assist your patient. For more information, please call 888.TEVA.USA
(838.2872). Some patients may be eligible for assistance from other programs. For a listing of these
other assistance programs go to: tevacades.org/OtherResources.aspx.

REIMBURSEMENT ASSISTANCE
CORE
CORE (Comprehensive Oncology Reimbursement Expertise) provides patients and providers with a reim-
bursement support program, as well as online tools to help make it easier to understand and navigate
reimbursement. The CORE Hotline (1.888.587.3263) is a service
provided by Teva Oncology to help physicians and their patients understand the complexities of reim-
bursement and where CORE fits in. Reimbursement consultants are available 9:00 am to 8:00 pm EST,
Monday through Friday, to provide assistance with the following:
• Benefit verification and coverage determination
• Pre-certification and prior autho-
rization support
• Coverage guidelines and claim requirements of payers
• Personalized support through the claims and appeals process
• Templates for letters of medical necessity
• Referral to the appropriate Teva Cares Foundation Patient Assistance Program.

Download the CORE enrollment form at: tevacore.com/PDF/Enrollment%20Form.PDF. Fax the completed form to 866.676.4073. Providers can also create an account and enroll their patients online at: https://eprescribe.iassist.com/?style=tevaoncology.
A web-based resource for caregivers, including the Prescription Drug Assistance Locator: agingcare.com/Articles/prescriptiondrugassistance-program-locator-171753.htm. This tool allows older adults and their families to search for financial aid programs for prescription medications. Search for prescription drug assistance plans by state or medication name or browse a list of nationwide non-profit prescription drug assistance programs.

BenefitsCheckUp*
benefitscheckup.org

A free service of the National Council on Aging (NCOA), a non-profit service and advocacy organization. Many adults over 55 need help paying for prescription drugs, healthcare, utilities, and other basic needs. There are over 2,500 federal, state, and private benefits programs available to help. BenefitsCheckUp asks a series of questions to help identify benefits that could save patients money and cover the costs of everyday expenses. After answering the questions, patients receive a personalized report that describes the programs that may help them. Patients can apply for many of the programs online or print an application form. Here are the types of expenses patients may get help with:

- Medications
- Food
- Utilities
- Legal
- Healthcare expenses
- Housing expenses
- In-home services
- Taxes
- Transportation
- Employment training.

If patients have Medicare and have limited income and resources, they may be eligible for the Medicare Rx Extra Help program. Patients may be able to get extra help paying for prescription drug costs if:

- Their income is less than $17,820 (if single) and $24,030 (if married). If they live in Alaska or Hawaii, they may still get help even if their income is higher than these limits.
- Patients have resources less than $13,640 (if single) and $27,250 (if married).

If patients meet the guidelines, they will have low or no deductibles, low or no premiums, no coverage gap, and will pay much less for prescriptions. At the same time, patients can start the application process for the Medicare Savings Programs that could increase their monthly income by about $121.80. Patients will also find out if there are other benefits programs that can save them money. Apply online at: www.benefitscheckup.org/cf/continue.cfm. For more information go to: benefitscheckup.org.

CancerCare*
cancercare.org

CancerCare provides limited financial assistance to people affected by cancer. As a non-profit organization, funding depends on the sources of support CancerCare receives at any given time. If CancerCare does not currently have funding to assist you, their professional oncology social workers will always work to refer you to other financial assistance resources. Check: cancercare.org periodically for funding updates. In order to be eligible for financial assistance patients must:

- Have a diagnosis of cancer confirmed by an oncology healthcare provider
- Be in active treatment for cancer
- Live in the U.S. or Puerto Rico
- Meet our eligibility guidelines of 250% of the Federal Poverty Limit.

Here’s how to apply:

1. Call 800.813.HOPE (4673) and speak with a CancerCare social worker to complete a brief interview, 9:00 am to 7:00 pm ET, Monday through Thursday, and 9:00 am to 5:00 pm ET on Friday.

2. If patients are eligible to apply, we will:
   - Mail the patient an individualized bar coded application
   - Request documentation to verify the patient’s income.
3. Patients must submit a completed application. Here are some tips:
   • Print clearly—illegible applications cannot be processed.
   • Fill in each blank space in the application. Use “no,” “none,” or “0” as appropriate—do not leave any blank responses.
   • Have a medical oncology healthcare provider complete all sections of the Medical Information Section and provide a signature and date. Patients cannot complete this section.
   • Make sure patients use the correct CancerCare mailing address and fax number listed on the application.

NOTE: CancerCare’s financial assistance does not cover basic living expenses such as rent, mortgages, utility payments, or food.

CancerCare*Co-payment Assistance Foundation
cancercarecopay.org

CancerCare Co-payment Assistance Foundation (CCAF) helps people afford the cost of co-payments for chemotherapy and targeted treatment drugs. This assistance is provided free of charge to ensure patient access to care and compliance with prescribed treatments. CCAF offers a seamless, same-day approval process through a state-of-the-art online platform. Patients will always know if they have been approved on the same day they apply. This allows immediate access to the full array of CancerCare support services, including telephone, online, and in-person counseling, support groups, information and resource referrals, publications, education, and financial assistance with treatment-related expenses such as transportation and child care.

In order to be eligible for assistance, patients must complete and sign an application and HIPAA Authorization form, as well as provide proof of income. CCAF will review your application and forms on a first-come, first-served basis to the extent that funding is available.

NOTE: as a non-profit organization, CCAF cannot guarantee that funding will always be available for a particular diagnosis. If unable to provide co-payment assistance, however, they will refer patients to other organizations that may be able to help.

To qualify for assistance, patients must meet the criteria below:
   • **Financial.** Individuals or families with an adjusted gross income of up to four times the Federal Poverty Level may qualify for assistance. CCAF may also consider the cost of living in a particular city or state. Income verification is required as part of the application process.
   • **Medical.** Patients must be diagnosed with one of the cancer types covered by CCAF (check the CCAF website for an up-to-date list of the types of cancers for which assistance is currently available). The treating physician must submit a verification form confirming diagnosis and medications. In addition, the physician must complete and sign our physician verification form. Patients must currently be undergoing chemotherapy or prescribed and/or using a targeted treatment drug when they apply to CCAF, and at the time of approval.
   • **Insurance.** Patients must be covered by private insurance or an employer-sponsored health plan, or they must have Medicare Part B, Medicare Part D, or a Medicare Advantage Plan (Medicare C).
   • **Other criteria.** Patients must be receiving treatment in the United States. Patients must be a U.S. citizen or legal resident.

NOTE: if patients have private insurance, please contact the drug company that manufactures their medication before you contact CCAF, as the company may offer a program that can help. Patients who are uninsured (do not have any insurance or medical plan that covers their prescription medicines), are not eligible for co-payment assistance. However, we encourage you to contact us at: 866.55.COPAY (866.552.6729), 9:00 am to 7:00 pm EST, Monday through Thursday, and 9:00 am to 5:00 pm EST on Friday, so that we can refer you to other organizations or patient assistance programs.

Eligible individuals will receive an application packet with instructions on how to apply for assistance. Co-payment specialists are available to answer questions about this process. Or patients can enroll...
online at: http://portal.cancercarecopay.org. CCAF provides easy access to enrollment and can provide same-day approval.

**Cancer Financial Assistance Coalition**
cancerfac.org

CFAC is a coalition of financial assistance organizations joining forces to help cancer patients experience better health and well being by limiting financial challenges, through:
1. Facilitating communication and collaboration among member organizations
2. Educating patients and providers about existing resources and linking to other organizations that can disseminate information about the collective resources of the member organizations
3. Advocating on behalf of cancer patients who continue to bear financial burdens associated with the costs of cancer treatment and care.

Because CFAC is a coalition of organizations, it cannot respond to individual requests for financial assistance. To find out if financial help is available, use the CFAC database at: cancerfac.org. Search by cancer diagnosis or specific type of assistance or need (i.e., general living expenses, transportation, childcare).

**Co-Pay Relief**
copays.org

The Patient Advocate Foundation (PAF) Co-Pay Relief Program (CPR) provides direct financial support to qualified patients, including those insured through federally administered health plans such as Medicare, assisting them with prescription drug co-payments, co-insurance, and deductibles required by the patient’s insurer. CPR call counselors work directly with the patient as well as with the provider of care to obtain necessary medical, insurance and income information to advance the application quickly. Upon approval, payments may be made to:
- The pharmacy
- The healthcare provider
- The patient directly.

Eligibility requirements:
- Patients must be insured and insurance must cover the medication for which they seek assistance.
- Patients must have a confirmed diagnosis of the disease or illness for which they seek financial assistance.
- Patients must reside and receive treatment in the United States.
- The patient’s income must fall below the income guidelines of the fund under which they are requesting financial assistance. All funds have income guidelines of either 300 percent, 400 percent, or less of the Federal Poverty Guideline with consideration of the Cost of Living Index and the number in the household.

NOTE: Patients will be informed immediately upon application if they qualify for assistance.

The CPR Program offers four points of entry:
1. Patients may apply via the Patient Online Application Portal available 24 hours a day.
2. Medical providers may apply on behalf of their patients via the Provider Online Application Portal available 24 hours a day.
3. Pharmacies may apply on behalf of their patients via the Pharmacy Online Application Portal available 24 hours a day.
4. The program offers personal service to all patients through the use of an Approval Specialist, personally guiding patients through the enrollment process toll free at 866.512.3861, Option 1.

**Good Days**
http://www.mygooddays.org/

Good Days has a mission to ensure no one has to choose between getting the medication they need and affording the necessities of everyday living. Good Days helps patients suffering from chronic diseases by providing financial support to patients who cannot afford the medications they need. Services include:
- Direct Financial Assistance for patients who cannot afford their medication. Good Days offers a same-day approval process, so patients know on the same day that they apply whether or not they have been approved. If approved, patients are given enough funding to cover their treatments for the balance of the calendar year.
- Premium Assistance to help patients find the insurance
coverage that is right for them.

- Travel Assistance through the Good Days Travel Concierge Program, which can help with transport, lodging and ancillary travel costs for patients who must travel to receive treatment.

Please note, because Good Days is a non-profit charitable organization, it cannot guarantee that funding for a specific disease state will be available. However, if unable to provide financial help, Good Days will refer patients to outside organizations that may be able to offer assistance instead.

For a list of covered diseases and medications go to: http://www.mygooddays.org/for-patients/diseases-and-medications-covered/. Enrollment applications can be downloaded online at: http://www.mygooddays.org/wp-content/uploads/2014/10/2016_Internet-Application_v20151012.pdf (English) or http://www.mygooddays.org/wp-content/uploads/2014/10/2016_Internet-Application_v20151012_SC_Spanish.pdf (Spanish). (Please note: Enrollment applications may change from year to year.) Or providers and patients can apply online at: healthwellfoundation.secure.force.com. Questions? Call 877.968.7233, Monday through Friday, 8 am to 5 pm CST.

**HealthWell Foundation**

healthwellfoundation.org

The HealthWell Foundation reduces financial barriers to care for underinsured patients with chronic or life-threatening diseases by providing financial assistance to eligible individuals to cover the cost of co-insurance, co-payments, healthcare premiums, and deductibles for certain medications and therapies. If patients have some healthcare coverage, either through a private insurance plan or a federal or state-funded program such as Medicare or Medicaid, but still cannot afford the out-of-pocket costs associated with their medical treatment, HealthWell may be able to help.

With the patient’s permission, providers, pharmacy representatives, and patient advocates can apply on behalf of a patient in two ways:

1. Apply online using the HealthWell provider portal at: https://healthwellfoundation.secure.force.com/
2. Apply by phone at: 800.675.8416.

**NOTE:** Providers, pharmacies, and social workers are strongly encouraged to use the Provider Portal to apply so that patients can readily access HealthWell hotline care managers. Before beginning the application process, have the following information ready:

- Patient contact information (name, address, telephone number, social security number, date of birth).
- Patient insurance and prescription information and ID (i.e., insurance and policy information and prescription card(s)).
- Patient income information (total household income, total household size)
- Prescribing physician information (name, address, telephone number, fax number, and contact name)
- Fund to which the patient is applying for assistance
- Type of assistance the patient is applying for (co-pay or premium)

**NOTE:** not all funds offer premium assistance.

The HealthWell Foundation provides instant approval for patients applying online or via phone. (Online applications can take up to one business day to process; patients and providers who apply over the phone can expect to know of their approval status within 10 to 15 minutes.) If approved, HealthWell will send an approval letter with the enrollment period dates and grant amount to the patient. The approval letter will provide the patient with a Reimbursement Request Form based on the type of assistance requested and instructions for submitting the reimbursement OR a pharmacy card (fund appropriate). In addition, HealthWell will fax a copy of the approval letter to the provider as long as their fax number was provided.

**NOTE:** If patient does not have a social security number, providers should call 800.675.8416 to speak with a HealthWell representative.

**NOTE:** The HealthWell Foundation randomly selects patients for income audits and confirmation of diagnosis. It is very important for patients to understand that if they receive a letter from Health-
Well at any time requesting income documentation, they must reply right away. If they don’t, payments on their grant will stop or their HealthWell Pharmacy Card will be de-activated. In addition, the patient will have to submit income documentation to HealthWell for any and every new grant moving forward. Individuals applying on behalf of a child for the pediatric assistance fund will not receive immediate grant approval. For more information on the Pediatric Assistance Fund application process visit: healthwellfoundation.org/pediatric-assistance-fund.

When a patient applies and is approved for assistance, the grant start date can be up to 30 days prior to the application date. All active grant recipients are welcome to re-enroll at the end of their grant cycle (one year) as long as assistance is still required and the individual still meets the program criteria and funding is available. Patients can begin the re-enrollment process no more than 3-4 weeks in advance of the end date of their current grant.

Questions? Call 800.675.8416 to speak with a HealthWell representative, 9 am to 5 pm EST, Monday through Friday.

The Leukemia & Lymphoma Society (LLS.org)

The Leukemia & Lymphoma Society (LLS) Co-Pay Assistance Program helps patients pay their insurance premiums and meet co-pay obligations. LLS can also help providers and patients find additional sources of financial support. The LLS Co-Pay Assistance Program offers financial help toward:

- Blood cancer treatment-related co-payments
- Private health insurance premiums
- Medicare Part B, Medicare Plan D, Medicare Supplementary Health Insurance, Medicare Advantage premium, Medicaid spend-down, or co-pay obligations.

To be eligible for Co-Pay Assistance, patients must:

✓ Have a household income at or below 500 percent of the U.S. Federal Poverty Guidelines as adjusted by the Cost of Living Index
✓ Be a United States citizen or permanent resident of the U.S. or Puerto Rico and be medically and financially qualified
✓ Have medical and/or prescription insurance coverage
✓ Have an LLS Co-Pay Assistance Program covered blood cancer diagnosis confirmed by a provider (See a list of covered diagnoses here: http://www.lls.org/support/financial-support/co-pay-assistance-program.)

Apply online at: https://cprportal.lls.org/

You can also apply or get more information about the LLS Co-Pay Assistance Program, by calling 877.557.2672 and speaking with a co-pay specialist who will provide personalized service throughout the application process.

NeedyMeds
needymeds.com

NeedyMeds is a non-profit information resource dedicated to helping people locate assistance programs to help patients afford their medications and other healthcare costs. Each program has its own qualifying criteria. To find a PAP that you may qualify for click on the brand name or generic name drug under the “Patient Savings” tab on the NeedyMeds website, or search for your medication name using the search feature in the upper lefthand corner of the screen. If using the “Patient Savings” tab:

1. Click on the first letter of the name of your medicine in the alphabet bar.
2. Click on the name of your medicine to find out if there is a Patient Assistance Program (PAP) available. If there is an active program available, a PAP icon will appear under the drug name.
3. Click on the PAP icon to access the eligibility and contact information for the program(s). In some cases, the program application form can be printed from the NeedyMeds website. Applications should be faxed or mailed directly to the PAP, not to NeedyMeds.
4. PAPs can also be found by searching the Program Name List OR by looking through the Company Name List, both found under the “Patient Savings” tab on the NeedyMeds website.
5. If an application form is available through a PAP, look for it in the Program Applica-
tions list. Look for all of your medications, not just the most expensive ones.

**Applications Assistance:**
If you need help filling out your applications, see our list of organizations that provide application assistance for free or a small fee here: [http://www.needymeds.org/local-programs](http://www.needymeds.org/local-programs). These organizations can help with such things as finding a program for your prescription medication, completing the application forms, and working with physicians who must sign the forms. You can find local programs in two ways:
1. Enter the patient’s zip code to find a program in their area or
2. Search by state.

If your medicine does not appear on the brand name or generic name lists, then it is not available through a PAP.

Other assistance options include:

- **Coupons, Rebates & More**
  are offered by various drug companies and may offer a rebate, discount or even free trial size of a medication. Offers for prescription medications require a doctor’s prescription. Offers can be found three ways: under Brand Name Drugs if a coupon icon appears under the drug name then click on the icon. They can also be found on the Coupons, Rebates & More page of the NeedyMeds website. Use the alphabet bar to find the medicine. Or do a category search for coupons by diagnosis or symptoms.

- **NeedyMeds Drug Discount Card**
  provides savings of up to 80% on many prescription medications. The card is free and available to everyone. There is no registration and your entire family can use the same card. Download a card and learn more about its benefits. Information on other drug discount cards are also available on the NeedyMeds’ website.

- **Diagnosis-Based Assistance:**
  [needymeds.org/copay_branch.taf](http://needymeds.org/copay_branch.taf).
  There are many government and private-funded programs that help with costs associated with a specific diagnosis. They may cover many types of expenses, including drugs, insurance co-pays, office visits, transportation, nutrition, medical supplies, child, or respite care. Some cover one specific diagnosis, while others cover whole categories (such as all types of cancers) or even all chronic medical illnesses. Some programs are national in scope, while others are limited to people in specific states. Most have some type of eligibility requirements, usually financial ones. NeedyMeds has compiled a database of diagnosis-based assistance programs that you or your patient can search. It’s best to search by the type of diagnosis. Other ways to search for assistance are by looking for programs that serve a specific geographical area. If you know the name of a specific program about which you want more information, you can also search by name of program.

**Assistance with Government Programs:**
Every state has programs to help needy families and individuals with the cost of healthcare. NeedyMeds has compiled a database of these state programs. The programs are available via the organization website. You can search these programs by clicking on a state, the District of Columbia, Puerto Rico, or Guam. Programs and their guidelines vary from state to state. NeedyMeds has also has a list of Medicaid Sites with a clickable map where you can learn more about Medicaid in your state, as well as general information on Medicare.

For all help line questions, send emails to info@needymeds.org or call our toll-free number: 1.800.503.6897.

**Partnership for Prescription Assistance**
[pparx.org](http://pparx.org)

The Partnership for Prescription Assistance (PPA) helps qualifying uninsured and underinsured patients connect to the right assistance programs so that they can get the medicines they need for free or nearly free. The Partnership for Prescription Assistance will help you find the program that’s right for your patient, free of charge.

**Step 1.** Tell us what medicines your patient takes. Go to: [www.pparx.org/gethelp/select-therapies](http://www.pparx.org/gethelp/select-therapies). Type the name of the medicine into the box and click the search button. Once the search is complete you can add one or more prescription drugs from your search to the My Medicines list, which appears on the right side of the page. Repeat this process until you have entered and selected all of the medicines.
Step 2. Tell us about your patient. Provide basic information about the patient and the type of drug coverage (if any) he or she currently has. Answer short questions, such as the patient’s residency, age, and household income, to see which patient assistance programs they may qualify for. You must answer all questions marked with an asterisk on this page for your patient to be considered. If you need assistance, please call 1.888.477.2669 Monday through Friday, from 9:00 am to 5:00 pm EST.

Step 3. Get your patient’s results. See which prescription assistance programs your patient may be eligible for and select the ones you would like to apply to.

Step 4. Complete the application process. Print, complete, and mail applications to each program your patient is applying to. You may download the applications directly from your computer or device or have them emailed to you.

PPA offers other resources, including:

- Searchable list of Patient Assistance Programs: pparx.org/prescription_assistance_programs/list_of_participating_programs
- A list of discount drug card programs at: pparx.org/prescription_assistance_programs/savings_cards
- Information about Medicare prescription drug coverage at: pparx.org/prescription_assistance_programs/medicare_drug_coverage
- Have recent natural disasters affected your patient’s ability to get access to their prescription medicines? Download the natural disaster worksheet: pparx.org/sites/default/files/Natural%20Disaster%20Worksheet_Final.pdf and PPA may be able to match your patient with a program to help them regain access to their medicines.

Patient Access Network Foundation
panfoundation.org

The Patient Access Network Foundation (PAN) facilitates access to medical treatment for patients with chronic, rare, or life-threatening illness. Providers and their patients can apply for assistance by calling 1.866.316.7263, between 9:00 am and 5:00 pm ET Monday through Friday, or start the application online through the Pan Foundation Provider Portal: https://providerportal.panfoundation.org/.

In order for patients to qualify for co-payment assistance with the Patient Access Network Foundation, they must meet the following eligibility criteria:

- Patient must be getting treatment for the disease named in the assistance program to which he or she is applying
- Patient is insured and insurance covers the medication for which the patient seeks assistance
- The medication or product must be listed on PAN’s list of covered medications
- Patient’s income must be below a designated percentage of the Federal Poverty Level, depending on individual fund requirements
- Patient must reside and receive treatment in the U.S. (U.S. citizenship is not a requirement.)

Step 1. Log into the correct Pan Foundation Portal (i.e., “Provider Portal,” “Patient Portal,” or “Pharmacy Portal”) to begin the application process.

Step 2. Select the appropriate disease fund for your patient. Select your patient’s primary insurance type from the drop-down list. Then, select the name of the medication for which you are applying for assistance.

Step 3. You will need to access to the following information for the patient:

Demographic information
- First and last name
- Social Security number or Alien Number
- Phone number
- Street address and email address.
Income Information
Documentation of adjusted gross income applicable to the patient and all members of the patient’s household. Such documentation may include:
- Tax forms (1040, 1040 EZ)
- Social Security statements (1099)
- Retirement income documentation (e.g., IRA and pensions)
- Other income sources (e.g., alimony, child support, rental income)

Insurance and Co-payment Information
- Health insurance card(s)
- Details regarding assistance that patient may be receiving from other co-pay or co-insurance assistance organizations.

NOTE: Patients should be prepared to share co-pay or co-insurance obligations for the medications relevant to the disease fund for which they are applying).

Step 4. You will need to access to the following information for the provider:
- First name
- Last name
- Phone number
- Facility address
- Email address.

Step 5. Review the application to make sure the information entered is correct and then submit the application online using the PAN Foundation Portal. For more information or to apply over the phone call 1.866.316.7263, between 9:00 am and 5:00 pm EST.

Patient Advocate Foundation
patientadvocate.org

The Patient Advocate Foundation (PAF) is a national non-profit organization that provides professional case management services to Americans with chronic, life threatening, and debilitating illnesses. PAF case managers, assisted by doctors and healthcare attorneys, serve as an active liaison between the patient and their insurer, employer, and/or creditors to resolve insurance, job retention, and/or debt crisis matters relative to their diagnosis. PAF seeks to safeguard patients through effective mediation assuring access to care, maintenance of employment, and preservation of their financial stability. PAF offers services by telephone, email, or web chat to patients in need that fall under the scope of our services. Professional staff members offer assistance via telephone, email, or live web chat to patients in need who fall under the scope of PAF’s services. Available patient services from Patient Advocate Foundation include:

Case management. Free one-on-one assistance with a professional case manager to help patients, caregivers, or providers resolve healthcare issues. Case managers are available to assist patients, caregivers, and their providers who face debilitating, chronic, or life threatening disease. Call toll free at 1.800.532.5274.

MedCare program. The MedCareLine is a division of Patient Advocate Foundation staffed with a team of nurses and case managers who provide individualized case management services to a specific population of patients, caregivers, and providers.

Financial aid fund division. This independent division of Patient Advocate Foundation provides small grants to patients who meet financial and medical criteria. Grants are provided on first-come first served basis and are distributed until funds are depleted. Qualifications and processes for each fund may differ based on fund requirements.

Co-Pay Relief Program. Operating as an independent division within PAF, the Co-Pay Relief Program offers co-pay assistance for insured applicants meeting disease and income eligibility guidelines to help patients afford the cost of pharmaceutical medications and treatments.

Partnership programs. PAF works in conjunction with many nonprofit and corporate partners, including but not limited to, American Cancer Society, Susan G. Komen, and Cancer Treatment Centers of America to meet the needs of patients across the United States.

Outreach & support programs. PAF performs community-based educational and outreach programs geared towards increasing access to quality healthcare for underserved populations. PAF also works to educate patients about resources focused on disease prevention and screening. Contact PAF to see when they will be in your area next.
RxAssist
rxassist.org

RxAssist offers a comprehensive resource center for patients, healthcare providers and patient advocates who are seeking free and low cost medications to help manage chronic diseases. The RxAssist database contains eligibility information and applications for over 150 pharmaceutical company patient assistance programs. The database can help you find out whether a drug is available, which pharmaceutical company program offers the drug, and how to apply for the medication. RxAssist also provides practical tools, news, and articles for patients and healthcare providers alike.

Using RxAssist

Step 1. In order to use the database, you must register either as a provider or patient. If you are already registered, login. Click the “Search Database” tab or find the search box in the Provider Center or Patient Center pages.

Step 2. Choose whether you want to search by drug name or company name. Or conduct a “multiple drug” search, which allows you to search for a drug by either the generic or brand name, and to choose between the Patient Assistance Programs database, which searches the charitable programs offered by pharmaceutical companies as well as RxOutreach and Xuben, or the Generics Retail Programs database, which searches generic drug programs offered through retail pharmacies.

To search for a medication by brand name or generic name, select “search by drug name.” Then, enter either the complete name of the medication, or the first few letters. If you type in the full name, the name must be spelled correctly in order for the database to find that medication. If you are unsure how to spell a drug name, type in as many letters as you know to be correct. If you type only the first letter, the results will include all generics and brand names that begin with that letter.

To search a company name, select “search by company name,” then type the company’s name into the search term box. To search the RxOutreach program select the “search by RxOutreach” button and follow the same instructions as those above for drug name. When searching by RxOutreach, the results will only include medications available through this program.

Step 3. If you would like to search for multiple drugs, click the advance search button. Then, enter the items in the search boxes that pop up.

Step 4. After you have entered information in the search box, if the database finds a match a search results page will appear. (If there is only one program available for a medication, you will be taken directly to the program details page.)

Step 5. Click the underlined hyperlink of the medication you want in the search results page, and you will be taken to the program details page.

Step 6. The program details page includes eligibility criteria and information on how to apply to the program. If an application is available for a program, you will see “Application Forms and Instructions” to the right with links to download the application.

Step 7. If an application is available online, you can either open (download) the application, type information directly onto the application on the screen and print it out, or print out the application and fill it out by hand. If there is no application online, use the phone number provided at the top of the program details page to call the company for information on how to get an application.

NOTE: RxAssist only includes medications that are available through patient assistance programs. If your medication is not listed, it most likely means that the medication is not available through a patient assistance program. If you believe that the program does exist, please contact RxAssist by emailing: info@rxassist.org. If a patient assistance program for the medication you have prescribed is not available, you or a patient advocate may contact the manufacturer of the medication directly to see if the medication could be sent to your patient.
RxAssist Prescription Discount Card

Patients can save up to 80 percent off the cash price of their medications using the RxAssist Prescription Discount Card at their local pharmacy. 21 of 25 most common meds are cheaper with the card than a $10 co-pay. This card:

• Is completely free and never expires
• Works for all FDA-approved prescription medications
• Supports RxAssist.org

Learn more at: rxassist.org/patients/patient-assistance-center.

RxHope™ rxhope.com

Healthcare providers and their staff can set up accounts online to order free medications for their patients through the RxHope automated patient assistance online system. If you would like to create a free account for one healthcare provider, visit: rxhope.com/Prescriber/Set upAccount.aspx. (NOTE: Each account is valid for use by one healthcare provider only. If multiple members of your office staff wish to utilize the RxHope automated patient assistance online system, each staff person must set up a separate account.) To set up your free account and place orders online the following criteria are required:

• You must be a healthcare provider or their staff
• A valid state license number for the healthcare provider
• An email address (this will become your login)
• The medication for which the patient is applying

• The patient’s first and last name.

Once you have the above information available, go to: www.rxhope.com/Prescriber/Register.aspx and follow the instructions. You will be setting up your free account and creating an order for your patient all at the same time.

Rx Outreach® rxoutreach.org

Rx Outreach is a fully-licensed non-profit mail order pharmacy that ships medication directly to patients’ homes. To make this process simple and cost-effective, Rx Outreach typically ships a 90 or 180-day supply of the needed medication. Patients who meet eligibility requirements can use Rx Outreach regardless of whether they use Medicare, Medicaid, or other health insurance. To be eligible to use Rx Outreach, patients must meet income requirements, which differ depending on household size:

• 1-person household: Less than $35,640 /year. (Alaska: less than $44,520 /year; Hawaii: less than $41,010/year.)
• 2-person household: Less than $48,060 /year. (Alaska: less than $60,060 /year; Hawaii: less than $55,290/year.)
• 3-person household: Less than $60,480 /year. (Alaska: less than $75,600/year; Hawaii: less than $69,570/year.)
• 4-person household: Less than $72,900 /year. (Alaska: less than $91,140 /year; Hawaii: less than $83,850/year.)
• More than 4-person household: For each additional person in the house, add $12,420/year. (Alaska: add $15,540/year; Hawaii: add $14,280/year.)

Providers and patients can enroll in the program by following the steps below:

1. Determine patient eligibility using criteria above.
2. See if the patient’s drug is listed on the RxOutreach Medication’s List: rxoutreach.org/find-your-medications.
3. Create a simple account by providing your email address and selecting a password. Verify the email address provided.
4. Enroll in Rx Outreach. To enroll, you’ll need to provide the following information:

• Name and contact information for provider and patient
• Patient date of birth
• Patient Social Security or Green Card number (required to order Controlled Substance medications only)
• Information on patient allergies and current medications
• Patient income and household size information
• For faster service, you can include credit card information for payment at this time.
5. Follow Rx Outreach guidelines, found at http://rxoutreach.org/wp-content/uploads/current/Overview.pdf, when writing patient’s prescription. It is important that the patient’s prescription is written according to these guidelines.
6. Calculate the cost of your medication(s) by filling out the worksheet found at [http://www.rxoutreach.org/](http://www.rxoutreach.org/), using the information provided here: [rxoutreach.org/find-your-medications](http://www.rxoutreach.org/).

7. Fill out and sign the Rx Outreach form. Patients will need to submit a separate form for each member of their household who orders medication. Medications can be sent directly to the patient’s home, or to the provider’s office. To obtain additional forms call 1.888.RXO.1234 (888.796.1234). Monday through Friday, 7 am to 5:30 pm CST or visit the Rx Outreach website.

8. Submit prescription, payment and form to Rx Outreach. Payment can be made with personal checks, money orders, or credit cards (only Visa, MasterCard, or Discover). Patients are asked not to send cash. Patients should send payment for the total cost of their medication(s) along with completed Rx Outreach form and prescriptions. (NOTE: If patient has health insurance, they cannot use their insurance to help pay the Rx Outreach fee.) Prescriptions and payment may be faxed to 1.800.875.6591. Faxed prescriptions are only accepted from a healthcare provider’s office or facility. Patients or providers can also mail prescriptions and payment to: Rx Outreach, P.O. Box 66536, St. Louis, MO, 63166-6536. Credit or debit card payment can also be submitted online or over the phone. Once payment and prescription are received, please allow 24 to 48 hours for processing.

For more information, go to: [rxoutreach.org](http://www.rxoutreach.org) or call 1.888.RXO.1234 (1.888.796.1234), Monday through Friday, 7:00 am to 5:30 pm CST.

### Tips for Assisting Patients in Applying to Patient Assistance Programs

- **If you have any questions,** call the program directly. Eligibility requirements, drugs, dosages, even programs, change regularly so it’s best to go directly to the program for information. If you do not qualify for the PAP but cannot afford your medicine, tell the representative. Some companies may make hardship exceptions and are willing to review situations on a case-by-case basis. Sometimes you can write an appeal letter to the program explaining your financial hardship.

- **Review the Federal Poverty Guidelines and Percentages over the Poverty Guidelines** when looking at the eligibility guidelines of a program.

- **Fill out as much information on the application as possible,** including the doctor’s address and phone number. Highlight the directions for the doctor and where he or she needs to sign. Give the doctor’s office an addressed-and-stamped-envelope to send in the application or highlight the fax number so it is easy to find.

- **Plan ahead so your medicine supply doesn’t run out.** When sending in an application, pay attention to the refill process and the amount of allowable refills. Each program is different; some require a call from the doctor’s office while another may allow the patient to call directly for a refill; others may require a new application, which takes time.

- **Be neat and complete.** The directions on the application should be completed exactly as directed. Print neatly. If something is unreadable or there is a blank, then the application may be denied, which can delay the process of receiving the medicine. Put “N/A” or “not applicable” in blanks that are not filled out to indicate the material was read through and not skipped over. Include supplementary forms if requested. Make sure all accompanying photocopies are clean and readable.

Source: The ACCC Financial Advocacy Network. accc-cancer.org/FAN.
**Important Safety Information**

**Contraindications**  XTANDI is not indicated for women and is contraindicated in women who are or may become pregnant. XTANDI can cause fetal harm when administered to a pregnant woman.

**Warnings and Precautions**

**Seizure**  In Study 1, conducted in patients with metastatic castration-resistant prostate cancer (CRPC) who previously received docetaxel, seizure occurred in 0.9% of XTANDI patients and 0% of placebo patients. In Study 2, conducted in patients with chemotherapy-naive metastatic CRPC, seizure occurred in 0.1% of XTANDI patients and 0.1% of placebo patients. There is no clinical trial experience re-administering XTANDI to patients who experienced a seizure, and limited safety data are available in patients with predisposing factors for seizure. Study 1 excluded the use of concomitant medications that may lower threshold; Study 2 permitted the use of these medications. Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity during which sudden loss of consciousness could cause serious harm to themselves or others. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

**Posterior Reversible Encephalopathy Syndrome (PRES)**  In post approval use, there have been reports of PRES in patients receiving XTANDI. PRES is a neurological disorder which can present with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably MRI. Discontinue XTANDI in patients who develop PRES.

**Adverse Reactions**

The most common adverse reactions (≥10%) reported from two combined clinical studies that occurred more commonly (≥2%) over placebo in XTANDI patients were asthenia/fatigue, back pain, decreased appetite, constipation, arthralgia, diarrhea, hot flush, upper respiratory tract infection, peripheral edema, dyspnea, musculoskeletal pain, weight decreased, headache, hypertension, and dizziness/vertigo.

In Study 1, Grade 3 and higher adverse reactions were reported among 47% of XTANDI patients and 53% of placebo patients. Discontinuations due to adverse events were reported for 16% of XTANDI patients and 18% of placebo patients. In Study 2, Grade 3-4 adverse reactions were reported in 44% of XTANDI patients and 37% of placebo patients. Discontinuations due to adverse events were reported for 6% of both study groups.

- Lab Abnormalities: Grade 1-4 neutropenia occurred in 15% of XTANDI patients (1% Grade 3-4) and 6% of placebo patients (0.5% Grade 3-4). Grade 1-4 thrombocytopenia occurred in 6% of XTANDI patients (0.3% Grade 3-4) and 5% of placebo patients (0.5% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of XTANDI patients (0.2% Grade 3-4) and 16% of placebo patients (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of XTANDI patients (0.1% Grade 3-4) and 2% of placebo patients (no Grade 3-4).
Significantly improved radiographic progression-free survival\(^1\)
- 83% reduction in risk of radiographic disease progression or death with XTANDI + GnRH therapy\(^*\) vs placebo + GnRH therapy\(^*\) (co-primary endpoint: HR = 0.17 [95% CI, 0.14-0.21]; P < 0.0001)
- Median radiographic progression-free survival was not reached (95% CI, 13.8-not reached) for XTANDI + GnRH therapy\(^*\) and was 3.7 months (95% CI, 3.6-4.6) for placebo + GnRH therapy\(^*\)

Significantly delayed the time to cytotoxic chemotherapy initiation\(^1\)
- Delayed time to cytotoxic chemotherapy initiation by a median of 28.0 months with XTANDI + GnRH therapy\(^*\) vs 10.8 months with placebo + GnRH therapy\(^*\) (HR = 0.35 [95% CI, 0.30-0.40]; P < 0.0001)

Effect of Other Drugs on XTANDI
Avoid strong CYP3A4, CYP2C9, and CYP2C19 substrates with a narrow therapeutic index, as XTANDI may decrease the plasma exposures of these drugs. If XTANDI is co-administered with warfarin (CYP2C9 substrate), conduct additional INR monitoring.

Oral, once-daily dosing with no required steroid co-administration\(^1\)
- Dosage: XTANDI 160 mg (four 40 mg capsules) is administered orally, once daily
- Steroids were allowed but not required\(^1\)

Effect of XTANDI on Other Drugs
Avoid CYP3A4, CYP2C9, and CYP2C19 substrates with a narrow therapeutic index, as XTANDI may decrease the plasma exposures of these drugs. If XTANDI is co-administered with warfarin (CYP2C9 substrate), conduct additional INR monitoring.

Please see adjacent pages for Brief Summary of Full Prescribing Information.

\(^1\)As seen in the PREVAIL trial (Study 2): a multinational, double-blind, randomized, phase 3 trial that enrolled 1717 patients with metastatic CRPC that progressed on GnRH therapy or after bilateral orchiectomy, and who had not received prior cytotoxic chemotherapy. All patients continued on GnRH therapy.\(^2\)
\(^2\)Results from this analysis were consistent with those from the prespecified interim analysis.

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Laboratory Abnormalities
In the two randomized clinical trials, Grade 1-4 neutropenia occurred in 15% of patients treated with XTANDI (1% Grade 3-4) and in 6% of patients treated with placebo (0.5% Grade 3-4). The incidence of Grade 1-4 thrombocytopenia was 6% of patients treated with XTANDI (0.3% Grade 3-4) and 5% of patients treated with placebo (0.2% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of patients treated with XTANDI (0.2% Grade 3-4) and 16% of patients treated with placebo (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 10% of patients treated with XTANDI (0.1% Grade 3-4) and 2% of patients treated with placebo (no Grade 3-4).

Infections
In Study 1, 1% of patients treated with XTANDI compared to 0.3% of patients treated with placebo died from infections or sepsis. In Study 2, 1 patient in each treatment group (0.1%) had an infection resulting in death.

Falls and Fall-related Injuries
In the two randomized clinical trials, falls including fall-related injuries, occurred in 9% of patients treated with XTANDI and included non-pathologic fractures, joint injuries, and hematomas.

Hypertension
In the two randomized trials, hypertension was reported in 11% of patients receiving XTANDI and 4% of patients receiving placebo. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in < 1% of patients in each arm.

Post-Marketing Experience
The following additional adverse reactions have been identified during post approval use of XTANDI. Because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure.

Neurological Disorders: posterior reversible encephalopathy syndrome (PRES)

DRUG INTERACTIONS

Drugs that Inhibit CYP2C8
Co-administration of a strong CYP2C8 inhibitor (gemfibrozil) increased the composite area under the plasma concentration-time curve (AUC) of enzalutamide plus N-desmethyl enzalutamide by 2.2-fold. Co-administration of XTANDI with strong CYP2C8 inhibitors should be avoided if possible. If co-administration of XTANDI with a strong CYP2C8 inhibitor cannot be avoided, reduce the dose of XTANDI.

Drugs that Induce CYP3A4
Co-administration of ritonavir (strong CYP3A4 inducer and moderate CYP2D6 inducer) decreased the composite AUC of enzalutamide plus N-desmethyl enzalutamide by 37%. Co-administration of strong CYP3A4 inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifabutin, rifapentine, rifabutin) with XTANDI should be avoided if possible. St John’s wort may decrease enzalutamide exposure and should be avoided. If co-administration of a strong CYP3A4 inducer with XTANDI cannot be avoided, increase the dose of XTANDI.

Effect of XTANDI on Drug Metabolizing Enzymes
Enzalutamide is a strong CYP3A4 inducer and a moderate CYP2C9 and CYP2C19 inducer in humans. At steady state, XTANDI reduced the plasma exposure to midazolam (CYP3A4 substrate), warfarin (CYP2C9 substrate), and omeprazole (CYP2C19 substrate). Concomitant use of XTANDI with narrow therapeutic index drugs that are metabolized by CYP3A4 (e.g., alfentanil, cyclosporine, diltiazem, ergotamine, fentanyl, imipramine, quinidine, sirolimus and tacrolimus), CYP2C9 (e.g., phenytoin, warfarin) and CYP2C19 (e.g., S-mephentanyl) should be avoided, as enzalutamide may decrease their exposure. If co-administration with warfarin cannot be avoided, conduct additional INR monitoring.

USE IN SPECIFIC POPULATIONS

Pregnancy—Pregnancy Category X.

Risk Summary
XTANDI can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals. While there is no human data on the use of XTANDI in pregnancy and XTANDI is not indicated for use in women, it is important to know that maternal use of an androgen receptor inhibitor could affect development of the fetus. Enzalutamide caused embryofetal toxicity in mice at exposures that were lower than those in patients receiving the recommended dose. XTANDI is contraindicated in women who are or may become pregnant while receiving the drug. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus and the potential risk for pregnancy loss. Advise females of reproductive potential to avoid becoming pregnant during treatment with XTANDI.

Animal Data
In an embryofetal developmental toxicity study in mice, enzalutamide caused developmental toxicity when administered at oral doses of 10 or 30 mg/kg/day throughout the period of organogenesis (gestational days 6-15). Findings included embryofoetal lethality (i.e., perinatal post-implantation loss and resorptions) and decreased anogenital distance at ≥ 10 mg/kg/day, and cleft palate and absent palatine bone at 30 mg/kg/day. Doses of 30 mg/kg/day caused maternal toxicity. The dose tested in mice (1, 10 and 30 mg/kg/day) resulted in systemic exposures (AUC) approximately 0.4, 0.4 and 1.1 times, respectively, the exposures in patients. Enzalutamide did not cause developmental toxicity in rabbits when administered throughout the period of organogenesis (gestational days 6-18) at dose levels up to 10 mg/kg/day (approximately 0.4 times the exposures in patients based on AUC).

Nursing Mothers
XTANDI is not indicated for use in women. It is not known if enzalutamide is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from XTANDI, a decision should be made to either discontinue nursing, or discontinue the drug taking into account the importance of the drug to the mother.

Pediatric Use
Safety and effectiveness of XTANDI in pediatric patients have not been established.

Geriatric Use
Of 1671 patients who received XTANDI in the two randomized clinical trials, 75% were 65 and over, while 31% were 75 and over. No overall differences in safety or effectiveness were observed between these patients and younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Patients with Renal Impairment
A dedicated renal impairment trial for XTANDI has not been conducted. Based on the population pharmacokinetic analysis using data from clinical trials in patients with metastatic CRPC and healthy volunteers, no significant difference in enzalutamide clearance was observed in patients with pre-existing mild to moderate renal impairment (30 mL/min ≤ creatinine clearance [CrCl] ≤ 60 mL/min) compared to patients and volunteers with baseline normal renal function (CrCl > 90 mL/min). No initial dosage adjustment is necessary for patients with mild to moderate renal impairment. Severe renal impairment (CrCl < 30 mL/min) and end-stage renal disease have not been assessed.

Patients with Hepatic Impairment
A dedicated hepatic impairment trial compared the composite systemic exposure of enzalutamide plus N-desmethyl enzalutamide in patients with baseline mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, or C, respectively) versus healthy controls with normal hepatic function. The composite AUC of enzalutamide plus N-desmethyl enzalutamide was similar in volunteers with mild, moderate, or severe baseline hepatic impairment compared to volunteers with normal hepatic function. No initial dosage adjustment is necessary for patients with baseline mild, moderate, or severe hepatic impairment.

OVERDOSAGE
In the event of an overdose, stop treatment with XTANDI and initiate general supportive measures taking into consideration the half-life of 5.8 days. In a dose escalation study, no seizures were reported at ≤ 240 mg daily; whereas 3 seizures were reported, 1 each at 360 mg, 480 mg, and 600 mg daily. Patients may be at increased risk of seizure following an overdose.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term animal studies have not been conducted to evaluate the carcinogenic potential of enzalutamide. Enzalutamide did not induce mutations in the bacterial reverse mutation (Ames) assay and was not genotoxic in either the in vitro mouse lymphoma thymidine kinase (TK) gene mutation assay or the in vivo mouse micronucleus assay.

Based on nonclinical findings in repeat-dose toxicity studies, which were consistent with the pharmacological activity of enzalutamide, male fertility may be impaired by treatment with XTANDI. In a 26-week study in rats, atrophy of the prostate and seminal vesicles was observed at ≥ 30 mg/kg/day (equal to the human exposure based on AUC). In 4-, 13-, and 29-week studies in dogs, hypospermatogenesis and atrophy of the prostate and epididymides were observed at ≥ 4 mg/kg/day (0.3 times the human exposure based on AUC).

Manufactured by: Catalent Pharma Solutions, LLC, St. Petersburg, FL 33716
Manufactured for and Distributed by: Astellas Pharma US, Inc., Northbrook, IL 60062

Revised: October 2015

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078-1200-PM

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Table 2. Adverse Reactions in Study 2 (cont.)
XTANDI® (enzalutamide) capsules for oral use
Initial U.S. Approval: 2012
BRIEF SUMMARY OF PRESCRIBING INFORMATION
The following is a brief summary. Please see the package insert for full prescribing information.

INDICATIONS AND USAGE
XTANDI is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

CONTRAINdications
Pregnancy
XTANDI can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals. XTANDI is not indicated for use in women. XTANDI is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus and the potential risk for pregnancy loss.

WARNINGS AND PRECAUTIONS
Seizure
In Study 1, which enrolled patients who previously received docetaxel, 7 of 800 (0.9%) patients treated with XTANDI experienced a seizure and no patients treated with placebo experienced a seizure. Seizure occurred from 31 to 603 days after initiation of XTANDI. In Study 2, 1 of 971 (0.1%) chemotherapy-naive patients treated with XTANDI and 1 of 844 (0.1%) patients treated with placebo experienced a seizure. Patients experiencing seizure were permanently discontinued from therapy and all seizure events resolved. There is no clinical trial experience re-administering XTANDI to patients who have experienced seizure.

Limited safety data are available in patients with predisposing factors for seizure because these patients were generally excluded from the trials. These exclusion criteria included a history of seizure, underlying brain injury with loss of consciousness, transient ischemic attack within the past 12 months, cerebral vascular accident, brain metastases, and brain arteriovenous malformation. Study 1 excluded the use of concomitant medications that may lower the seizure threshold, whereas Study 2 permitted the use of these medications.

Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

Posterior Reversible Encephalopathy Syndrome (PRES)
There have been reports of posterior reversible encephalopathy syndrome (PRES) in patients receiving XTANDI. PRES is a neurological disorder that can occur with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably magnetic resonance imaging (MRI). Discontinue XTANDI in patients who develop PRES.

ADVERSE REACTIONS
Clinical Trial Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Two randomized clinical trials enrolled patients with metastatic prostate cancer that has progressed on androgen deprivation therapy ( GnRH therapy or bilateral orchiectomy), a disease setting that is also defined as metastatic CRPC. In both studies, patients received XTANDI 160 mg orally once daily in the active treatment arm or placebo in the control arm. All patients continued androgen deprivation therapy. Patients were allowed, but not required, to take glucocorticoids.

The most common adverse reactions (≥ 10%) that occurred more commonly (≥ 2% over placebo) in the XTANDI-treated patients from the two randomized clinical trials were asthenia/fatigue, back pain, decreased appetite, constipation, arthralgia, diarrhea, hot flush, upper respiratory tract infection, peripheral edema, dyspnea, musculoskeletal pain, weight decreased, headache, hypotension, and dizziness/vertigo.

Study 1: Metastatic Castration-Resistant Prostate Cancer Following Chemotherapy
Study 1 enrolled 1199 patients with metastatic CRPC who had previously received docetaxel. The median duration of treatment was 8.3 months with XTANDI and 3.0 months with placebo. During the trial, 48% of patients on the XTANDI arm and 46% of patients on the placebo arm received glucocorticoids.

Grade 3 and higher adverse reactions were reported among 47% of XTANDI-treated patients and 53% of placebo-treated patients. Discontinuations due to adverse events were reported for 16% of XTANDI-treated patients and 18% of placebo-treated patients. The most common adverse reaction leading to treatment discontinuation was seizure, which occurred in 0.9% of the XTANDI-treated patients compared to none (0%) of the placebo-treated patients. Table 1 shows adverse reactions reported in Study 1 that occurred at a ≥ 2% higher frequency in the XTANDI arm compared to the placebo arm.

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>XTANDI N = 800</th>
<th>Placebo N = 399</th>
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</thead>
<tbody>
<tr>
<td>Grade 1-4 (%)</td>
<td>Grade 3-4 (%)</td>
<td>Grade 1-4 (%)</td>
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<tr>
<td>Hot flush</td>
<td>20.3</td>
<td>10.3</td>
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<tr>
<td>Hypertension</td>
<td>6.4</td>
<td>2.1</td>
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</tbody>
</table>
| Nervous System Disorders
| Headache        | 12.1           | 5.5            | 1.8           | 0.1 |
| Dizziness       | 9.5            | 7.5            | 4.1           | 2.3 |
| Spinal Cord Compression and Cauda Equina Syndrome |
| Paresthesia     | 6.6            | 4.5            | 3.5           | 2.4 |
| Mental Impairment Disorders
| Depression      | 4.3            | 1.8            | 1.8           | 0.8 |
| Hypoesthesia    | 4.0            | 1.8            | 1.8           | 0.8 |
| Infections And Infections
| Upper Respiratory Tract Infection |
| Lower Respiratory Tract And Lung Infection |
| Psychiatric Disorders
| Insomnia        | 8.8            | 6.0            | 4.0           | 2.0 |
| Anxiety         | 6.5            | 4.0            | 3.5           | 1.5 |
| Renal And Urinary Disorders
| Hematuria       | 6.9            | 4.5            | 4.0           | 2.0 |
| Poliakiauria     | 4.8            | 2.5            | 4.0           | 2.0 |
| Injury, Poisoning And Procedural Complications
| Fractures       | 4.0            | 0.8            | 4.0           | 0.8 |
| Skin And Subcutaneous Tissue Disorders
| Pruritus        | 3.8            | 1.3            | 3.8           | 1.3 |

Table 1. Adverse Reactions in Study 1

Study 2: Chemotherapy-naive Metastatic Castration-Resistant Prostate Cancer
Study 2 enrolled 1717 patients with metastatic CRPC who had not received prior cytotoxic chemotherapy, of whom 1715 received at least one dose of study drug. The median duration of treatment was 17.5 months with XTANDI and 4.6 months with placebo. Grade 3-4 adverse reactions were reported in 44% of XTANDI-treated patients and 37% of placebo-treated patients. Discontinuations due to adverse events were reported for 6% of XTANDI-treated patients and 6% of placebo-treated patients. The most common adverse reaction leading to treatment discontinuation was fatigue/asthenia, which occurred in 1% of patients on each treatment arm. Table 2 includes adverse reactions reported in Study 2 that occurred at a ≥ 2% higher frequency in the XTANDI arm compared to the placebo arm.

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
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<th>Placebo N = 844</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1-4 (%)</td>
<td>Grade 3-4 (%)</td>
<td>Grade 1-4 (%)</td>
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<tr>
<td>Hot flush</td>
<td>18.0</td>
<td>7.0</td>
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<tr>
<td>Dizziness</td>
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<tr>
<td>Mental Impairment Disorders</td>
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<td></td>
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<tr>
<td>Depression</td>
<td>5.7</td>
<td>1.3</td>
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<tr>
<td>Respiratory Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspnea</td>
<td>11.0</td>
<td>8.5</td>
</tr>
</tbody>
</table>
| Infections And Infections
| Upper Respiratory Tract Infection |
| Lower Respiratory Tract And Lung Infection |
| Psychiatric Disorders
| Insomnia        | 8.2            | 5.7            | 8.2           | 5.7 |
| Renal And Urinary Disorders
| Hematuria       | 8.8            | 5.8            | 8.8           | 5.8 |
| Injury, Poisoning And Procedural Complications |
| Non-Pathological Fractures |
| Metabolism and Nutrition Disorders
| Decreased Appetite |
| Investigations |
| Reproductive System and Breast Disorders
| Gynecostasia     | 3.4            | 1.4            | 3.4           | 1.4 |