GLEEVEC PATIENT ASSISTANCE PROGRAM USA
Patient Guide

Joan D. Ramos, MSW
Cancer Resources & Advocacy
Seattle, WA

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Introduction:

When Gleevec was approved by the FDA in May of 2001, the CEO of Novartis, Daniel Vasella, announced to the public that no patient would be denied access to Gleevec for financial reasons. This was particularly significant not only because of the treatment potential of this new drug, but also because of its cost. At that time, the average cost was estimated to be $2500/month, depending on dosage. The current average price is probably closer to $3500, depending on dosage and source. Novartis put in place a Patient Assistance Program (PAP) for Gleevec to process requests for patients living in the USA. A separate international program was established for patients outside the USA called GIPAP.

Gleevec PAP

To carry it out, Novartis contracted with a specialist company called Documedics to run the PAP for them. A toll-free hotline was set up to take calls from patients needing help to acquire Gleevec. The number is:

1-877-GLEEVEC or 1-877-453-3832
Hours: Monday-Friday from 9 a.m.- 8 p.m. EST

Novartis set up eligibility criteria for the Gleevec PAP, which are as follows:

Patient must be a U.S. resident who either has no insurance or only a limited pharmacy benefit.

Patients and their physicians must complete eligibility forms and allergy sheet, to assure that the patient will not react adversely to Gleevec.

The plan administrator, Documedics, will verify the income and assets of each patient, to confirm eligibility.
Patient's annual household income must be less than 500% of the current federal poverty level, and must have assets that do not exceed $75,000 (excluding first home and car). Applicants will be asked for documentation.

Uninsured patients with annual household incomes of less than $43,000 will receive Gleevec at no charge.

The level of assistance provided will vary according to the number of dependents per household and income and expenses. In a one-person household, the cap is $100,000 income.

No household will be asked to contribute an amount greater than 20 percent of their gross annual income.

Patients who have a limited prescription drug benefit may apply for the PAP when they have exhausted their prescription benefit. It would not be unusual for such patients to enter into and out of the program from year to year, as the benefit is renewed and then expended.

Source: Novartis cited in www.cmlsupport.com

A little about PAPs

PAPs have become common in the USA in recent years as drug companies attempt to react to criticism that the prices they charge for drugs are too high and given the reality of many uninsured and underinsured people who need medicines. Efforts are underway to try to remedy the situation, but a solution will be some time in coming. Particularly hard hit are not only the uninsured but also disabled people and senior citizens covered by Medicare that currently offers no prescription coverage at all. Working people who do have insurance often find that they too have a limited or no prescription drug benefit. Since cancer patients usually need to take several medications at any given time, the cost can be significant. Some drug companies have introduced drug discount cards and others offer PAPs, usually restricted only to patients with poverty-level incomes. The Novartis program is among the first to offer help to a broader range of patients, and the company has stated on numerous occasions that it wants to make the costly Gleevec available to all who need it.

Novartis has stated that the PAP is also for patients with a “limited pharmacy benefit”, as well as that no one would be denied coverage for financial reasons. This promise has been reported widely in the media, and in Novartis’ own company publications. For example, in their 2001 Annual Report:

Applying to the Gleevec PAP: Tips for Success

Doing your homework in advance of applying to the program will enhance your chance of being accepted. It is necessary to understand how the PAP works and what your responsibilities are to provide the necessary documentation that establishes your need for help. Below is a list of steps you can take to prepare for the application process. Be sure also to keep your own records, with dates, of all contacts made with the program including phone calls, mail, e-mail, and names of people you speak with.
The following guidelines may not apply to all patients, but they will help you get organized and plan your strategy. You will have a better chance of success if you can line up the paperwork and/or work with the relevant people in the following areas:

1. **Documents:** Copy the documents needed to verify your income (such as income tax returns), number of dependents, monthly expenses, employment or disability status, list of all medications you have been prescribed and how you pay for them, and your physician’s prescription for Gleevec. Depending on your income level, you may need to show records of your personal assets as well. This applies to both uninsured and insured patients.

2. **Insurance:**
   - Obtain a copy of your health insurance contract, not just the booklet given to plan members. If your insurance is through your job, your employer’s the human resources person can obtain this for you, as well as assist you in the trouble-shooting process. You need to know exactly what is and is not covered under your plan.
   - Make copies of your insurance card, Medicare and/or Medicaid card, etc.
   - Find out if within the insurance company there is a case manager (often designated for those with serious illnesses) who can be assigned to you, or at least one individual who can handle your claims and inquiries. Explain to this person if you are having a problem getting Gleevec. Sometimes exception can be made to limits in coverage.

3. **Employer**
   - If your insurance is through an employer, that company may be an ally in your quest to obtain help in getting Gleevec. They can act on your behalf with the insurance company, asking for clarification on coverage or limitations and also ask for an exception. Most employers know that helping their employees and their family members will result in more productive and reliable workers. There might also be an employee assistance program though your workplace to whom you can turn for logistical help, in addition to the Human Resources department.

4. **Oncologist’s office:**
   - Be sure to ask for help from your oncologist and his/her staff. If you are being treated at a medical center, there may be an oncology social worker available to help you. If you see a community oncologist, it will probably be the nurse who is the one to assist you. Also be sure to mention to the oncologist if you are having difficulty paying for Gleevec. S/he can be an important ally and can assist with sending needed letters explaining your situation.
   - Ask someone from the doctor’s office to call the Gleevec hotline on your behalf right away. It’s a good idea to arrange for the call to be made while you are present, so that you can provide the hotline representative with your personal details. Usually they tell callers that they can divulge eligibility guidelines only to the patient.
   - If you have insurance but cannot afford co-pays, or have no or limited prescription coverage, have exhausted your benefits, etc, be sure to explain that. Also, PAPs are supposed to take into account the circumstances of the individual. You will need to back everything up with documentation of course.

**Problems getting Gleevec**

Since the start of 2003, an increasing number of patients in the USA have been reporting difficulty obtaining Gleevec on this and other Internet discussion lists. Reports are starting to surface of cancer patients being turned down by the Gleevec PAP simply because they have health insurance, despite the assurances to the contrary. The price of Gleevec appears to have increased in 2003 in the USA as well as in other countries. In addition, some patients who
previously were accepted into the program are reporting significant delays in getting refills. The difficulties being reported by patients fall mostly into the following scenarios:

Delays in handling of refill requests for those already on the program. Patients have reported being left without their medication for weeks due to not receiving renewal paperwork in a timely fashion.

Patients covered by Medicaid have been prescribed Gleevec but have great difficulty finding a pharmacy in their area that will fill the prescription.

New patients with insurance have found that their insurance plan has taken Gleevec off the formulary entirely and requires them to request it through a special pre-authorization process.

Reduction of coverage so that patients are being asked to make co-payments of $1000-$1500/month for their Gleevec supply. These patients report being told by the Gleevec PAP Hotline that they are not eligible for assistance even if they cannot afford the out-of-pocket expense.

Patients who are veterans being referred to the Veterans Administration by the Gleevec Hotline, only to learn that the VA now has a freeze on accepting new patients who do not have a previously-documented service-connected disability.

Patients being asked to pay the entire cost of Gleevec at the pharmacy each month, then apply for reimbursement, a process which can take up to 3 months or more. They too report being told that they are not eligible for the PAP because they have insurance

**Renewing your prescription under the Gleevec PAP**

If you have previously been approved for a free or reduced supply of Gleevec, you will be sent a 3-month supply of medicine. Your physician must send results of your quarterly lab tests to the Gleevec PAP in order for you to continue to receive the drug. Your financial eligibility will be re-evaluated every year.

Since patients have been reporting that they do not receive the renewal forms (either for the medical or financial information or both) in a timely manner, it is important for you to keep on top of the situation to ensure a continued supply of your medicine. If you have not received paperwork from the Gleevec PAP by the middle of the second month of each quarter, call the Hotline immediately and ask for it. For the financial forms, be sure to ask for them by the 10th month that you have been on the program. And be sure to have your own updated financial documents copied & ready to submit. Keep a paper trail: a dated log of all phone calls you make & all mail you receive regarding your case.

The tips below for those who are having trouble getting approved may be helpful to you also.

**What you can do if turned down for the Gleevec PAP:**

If you are experiencing problems in being able to purchase the Gleevec that has been prescribed for you by your oncologist, and have been told by the Gleevec PAP Hotline personnel that you’re not eligible for their program, don’t despair. There are a number of steps that you can still take to try to remedy the situation.

If you have taken the steps listed above and find that you are still turned down by the Gleevec PAP, then it will be necessary to ask for help in other ways. As mentioned before, the person who answers the phone at the Gleevec Hotline is not a Novartis employee, but a worker for a company with whom Novartis has contracted to run the program. Therefore the Hotline person does not have the final say regarding your acceptance into the program.
You may now wish to contact the following:

1. Your State **Insurance Commissioner**, who oversees all polices sold in your state. S/he can determine whether your insurer is upholding the terms of coverage to which it agreed when it was given permission to offer insurance. You can find the phone number for the insurance commissioner’s office in the government section of your telephone book or on the official state website.

2. **Novartis** Pharmaceuticals has designated the Director of Public Relations for Gleevec/Glivec as the liaison for patients having difficulties accessing either the international or USA PAP, which are administered separately. Her name is Gloria Stone at she may be reached at gloria.stone@pharma.novartis.com, or by phone at, 862-781-5587
   The Director of PAPs at Novartis is Edward Gajewski, at e-mail edward.gajewski@pharma.novartis.com

   The company mailing address is:

   Novartis Pharmaceuticals Corporation
   59 Route 10
   East Hanover, NJ 07936-1080
   Toll-free number: 1-888-669-6682 for Novartis Oncology

3. Your state and federal **elected officials** may be able to help you with some systems troubleshooting as well. Not only that, they have a vital interest in knowing how their constituents are faring. They need to hear from you as they consider proposed legislation that would and change the way that health care is made available to the American people and remedy the current crisis situation.

4. The **media**, local and/or national. If all else fails, you may decide you want to bring your case to the attention of the media. as a last resort. Both insurance and drug companies want to avoid negative publicity at all costs. Not every patient wants to become a public figure of course, but it is an option to consider, that has helped people in many other difficult situations.

   Good luck and be sure to let the moderators of the cancer discussion list you participate in know how things have turned out for you. The Internet is a powerful communication tool for patients and their loved ones, and is helping people around the world call attention to access to treatment problems and work for solutions.