

Patient Assistance

PROGRAM PRIMER



The private benefits plan sponsor's guide
to the patient assistance program

Access to care

Patient assistance programs help remove barriers to treatment



The weeks and months following the diagnosis of a serious medical condition can be an emotional roller coaster for patients and their caregivers. The resulting distress can be a major barrier to regaining balance in one's personal and professional lives, particularly when issues emerge that delay, or even threaten, access to treatment.

Patient assistance programs can smooth the way. Most programs are available through pharmaceutical companies to help eligible patients access their medications; programs are also offered by not-for-profit health charities, hospitals and government health agencies.

Patient assistance programs typically provide much more than financial assistance. Most employ trained staff, including health-care professionals, who are experienced in one-on-one patient support. Some providers, including pharmaceutical companies, use their own specialized

staff to support patients in a completely confidential manner; others outsource these services to specialty firms. Depending on the program, patients may access support through a call centre or they may be paired with a dedicated personal co-ordinator.

Patient assistance programs should not be confused with health case management programs, a relatively new drug-plan management strategy in the Canadian private sector. Health case management is mandatory for patients with complex treatment plans that include high-cost specialty medications. As a condition of coverage, patients and their doctors work with a payer-assigned health case manager, who assesses the effectiveness of the treatment plan. The case manager can also recommend alternative treatment options and refer patients to government or pharmaceutical-company patient assistance programs to supplement or offset private plan coverage.



Financial Assistance

While pharmaceutical-company patient assistance programs offer a broad range of supports, financial assistance is usually the first thing that comes to mind. Much like benefits offered by employers, the scope and type of financial assistance varies by company and by drug. The following pages describe the types of financial support a program may offer.

Brand choice

When a brand-name drug's patent expires, lower-cost generic drugs enter the market at a price that is usually lower than the brand-name drug. If a patient has a generic drug plan, the lower-cost generic drug is the default or "reference" price paid by the private plan. If plan members choose the brand-name drug over the generic, they have to pay the difference between the brand and generic prices as a co-payment to the pharmacist.

To support the continued sale of their brand-name drugs, pharmaceutical companies may offer patient assistance programs that encourage people to continue to use their drugs once generic alternatives are available. They do so by offering cards that behave much like coupons used for groceries. The cards are programmed to act as an additional payer in the drug-claim transaction and pay the cost difference between the generic and brand-name drug for patients whose plan only reimburses the cost of the generic.

Sampling

Pharmaceutical companies often produce sample sizes of their medications that physicians can offer to patients as a trial before they purchase a regular supply. Samples for biologic drugs are also possible; however, they require a different approach. Because biologic therapies are injected, or infused,

and require special handling and refrigeration, they can't be stored safely in a physician's office or patient's home. Rather than a physical sample, biologic drug manufacturers provide specialists with sample cards to give to their patients. The patient takes this card to a specialty pharmacy or infusion clinic to receive a sample of the biologic drug.

Biologic drug manufacturers provide specialists with sample cards to give to their patients, who bring this card to a specialty pharmacy or infusion clinic to receive a sample of the biologic drug.

Financial or co-pay assistance

Private drug plans may require members to pay co-insurance, or a co-pay, before coverage kicks in. For

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RxHelp™ programs

RxHelp™ programs offered through www.RxHelp.ca (a well-recognized Canadian website connecting patients to pharmaceutical-company-supported assistance programs) provide savings on brand-name prescription medicines. When the RxHelp™ card is used with a valid prescription, patients immediately receive payment assistance. In 2012, Canadians who used RxHelp™ card programs saved over \$50 million on 1.2 million brand-name prescriptions.

RxHelp.ca offers several types of card programs. "Patient Choice" cards allow patients to remain on their brand of choice at little or no additional cost over the generic version. "Patient Assistance" cards help offset or reduce the out-of-pocket patient costs that are not covered by patients' public or private drug plans.

The RxHelp™ website provides a searchable database that allows patients to search by drug name to determine if a program is available for their brand medication and provides details on the payment assistance that the program offers. In the past year, 91% of pharmacies have accepted RxHelp™ cards. For patient convenience, the website also offers a pharmacy locator that allows patients to easily find a nearby pharmacy that accepts and/or distributes RxHelp™ cards.

Patient-specific information is used only for adjudication and auditing purposes and is not shared with third parties. Also, no one, including the patient or the public or private payors, is obligated to pay any more than they are willing to pay for the product dispensed.

Patients can use the Internet or phone to order a free RxHelp™ card, which will arrive by mail in five to 10 business days. Many RxHelp™ programs allow patients to print a card or have one downloaded to their smartphone for immediate use. Cards are free of charge with no hidden fees or monthly charges, and patient privacy is protected.



Cards, cards, cards

Plan members with pay-direct drug plans receive pay-direct drug cards from their employers, which are presented to the pharmacist when filling their prescriptions. The card includes a contract or plan number that is assigned to their plan sponsor (typically their employer) and a unique member identification or certificate number that the pharmacist keys into the pharmacy system to determine a prescribed drug's level of coverage under the private plan. If a plan member's spouse also has a pay-direct drug plan, he or she can present the second card so the pharmacists can co-ordinate the claim with the second payer and adjudicate the total coverage available. The completed transaction tells the pharmacist how much each payer will reimburse for the drug and what amount, if any, they need to collect from the plan member as a co-payment at the point of sale.

Within this system, pharmaceutical companies can issue their own cards to provide various forms of financial support to those enrolled in their patient assistance programs. The contract number is assigned to a pharmaceutical company instead of a private plan. Depending on the program and the drug, the card can be used in conjunction with other pay-direct cards as part of adjudication or it can be the sole card presented (for instance, when private coverage is not available).

example, if someone needs a biologic drug that costs \$30,000 per year and their plan's co-insurance rate is 20%, or \$6,000, the drug could become unaffordable for them. Some patient assistance programs target their financial assistance to cover the cost of co-insurance. The level of assistance may be based on an assessment of the patient's financial situation. There is no industry standard on this type of financial assistance, if assistance is even offered, and the amount available varies by drug and pharmaceutical company.

Assistance and bridging

In rare situations, patients may receive what's referred to as "compassionate assistance" or "bridging" to help them access their medication. Bridging fills gaps in the supply of a medication during a defined period of need. For example, if a patient changes jobs while taking a medication that has been covered by their previous employer's private plan, there may be a waiting period of three months before coverage by their new employer's drug plan begins. During that time, the patient may not be able to afford to pay out of pocket for his or her medication, so the program bridges that gap by providing a three-month supply of medication to ensure continued treatment and avoid the deterioration of the patient's health during the transition.

Compassionate assistance may be available to participants in clinical trials. When a drug's clinical trial comes to an end, participants may not have private or public coverage, or be able to pay for the drug out of pocket. In this situation, the program may provide compassionate financial assistance so the patient can continue to experience the positive health outcomes achieved during the clinical trial.

Additional expenses

Although the Canadian health-care system is primarily publicly funded, patients may incur many additional expenses during treatment. For example, patients who live in remote areas have to travel a fair distance to get treatment. Even if services are close by, parking costs at medical facilities and hospitals can add up. Patients may not have access to a car or may not be able to drive due to their condition, and some symptoms limit their mobility and their ability to take public transit. Without a support system, these patients may have to rely on costly taxis to get to their medical appointments. To fill this need, patient assistance programs can co-ordinate transportation or reimburse patients for travel costs incurred for medical or infusion appointments. Patients greatly value this type of support to help them manage the often unanticipated incidental costs of treatment.

Overcoming obstacles to care

As a third-year student at Simon Fraser University in B.C., Kadi Nicholson filled her first prescription for Enbrel® (etanercept), a biologic for rheumatoid arthritis. Since then, Nicholson has received both educational and financial support from Amgen Canada's Enliven® patient assistance program, available to those with a prescription for Enbrel®.

To allay Nicholson's initial concerns about using the Enbrel® SureClick® Auto-injector, one of the program's nurses provided training at her university residence. The nurse also suggested ways to coordinate her study schedule and social life with medication dosing. "She answered all my questions and provided the support I needed so I could be an independent young adult and manage my disease," says Nicholson.

With her symptoms under control, Nicholson could plan for her future. She decided to become a physiotherapist to help others who are dealing with movement disorders and chronic conditions. To do so, she moved to Kingston, Ont., in September 2013 to complete the postgraduate physiotherapy program at Queen's University.

The move posed a challenge regarding access to her medication, since B.C.'s PharmaCare plan requires covered drugs to be purchased in the province. This was no longer a practical option for Nicholson. Nicholson contacted the Enliven® program, where staff helped her apply for coverage from Ontario's Drug Benefit plan. Enliven® provided a supply of Enbrel® so that Nicholson didn't have to go without treatment during Ontario's three-month waiting period for coverage.



Other Patient Supports

In addition to financial assistance, patient assistance programs can provide numerous logistical and educational supports that can be a tremendous boon to patients.

These are summarized on the following pages.

Physician concierge

Patients with serious diseases may have to wait months to see specialists; meanwhile, specialists report less time for patient care due to the amount of paperwork they must complete for patient reimbursement. Some programs provide trained nursing staff to help physicians complete this paperwork, which frees physician and office-staff time to see more patients.

Patient training

For biologic drugs, patients or their caregivers may need specialized training to deliver the medication. Unfortunately, the current health-care system may not be able to support the additional training and services required; therefore, patient assistance programs have become available. For example, a registered nurse will train patients or caregivers on how to give injections and educate them on dosing, safety and side effects. This support also frees physician and nursing-staff time for more patient care.

Less paper, more care

Quick access to treatment is top of mind for physicians, yet paperwork—particularly for medications that require special authorization—can get in the way. That’s why physicians appreciate the availability of patient assistance programs to help get the documentation in order.

Dr. Jonathan Adachi, a rheumatologist in Hamilton, Ont., cites the value of the administrative support he gets from Amgen Canada’s Enliven® patient assistance program for Enbrel® (etanercept), for example. “I’m a busy clinician and there is always paperwork waiting to be completed. Because the Enliven® program have case managers who can assist with the completion of the necessary forms and letters for reimbursement, patients often receive treatment much more quickly and it frees up my time to see other patients with rheumatoid arthritis in need of treatment.”

As well, the reimbursement specialists immediately investigate drug reimbursement options, which is also critical for timely access to treatment.

Dr. Adachi adds that patient assistance programs can be a key part of his practice. Referring again to Enliven®, the program can arrange for tests when he is determining a patient’s suitability for Enbrel®. When prescribing the drug, Dr. Adachi refers patients to the program’s primary point-of-contact case manager, who helps ensure they get the educational and treatment support they need on an ongoing basis. For example, they can schedule a trained nurse to provide one-on-one injection training.

Patient disease education

When patients are diagnosed with a serious illness, they or their caregivers seek information about the condition and rely on a wide variety of sources, such as the Internet and their network of family and friends. However, it can be difficult to find reliable easy-to-understand information. To fill that gap, many patient assistance programs employ trained health-care professionals to offer disease education in person, over the phone or online. User-friendly websites with content endorsed by health-care experts may also be available. This type of support provides credible, reliable medical information that might not otherwise be readily available.

Risk-management programs

If a new drug is known to have potentially severe side effects, Health Canada may require the pharmaceutical manufacturer to set up a risk mitigation program (RMP) as a condition of approval to minimize known risks and identify new risks in a post-market setting. The RMP is frequently integrated as part of a patient assistance program, and it may require physicians and pharmacists to complete training before they can prescribe or dispense the product. The RMP may also require a closed distribution chain using specialized wholesalers, distributors and pharmacies to closely monitor access to the product and to track patient outcomes and adverse events. Essentially, an integrated patient assistance and risk-management program establishes a controlled environment to ensure patient safety while accessing a much-needed medication.

Reimbursement investigation/ co-ordination

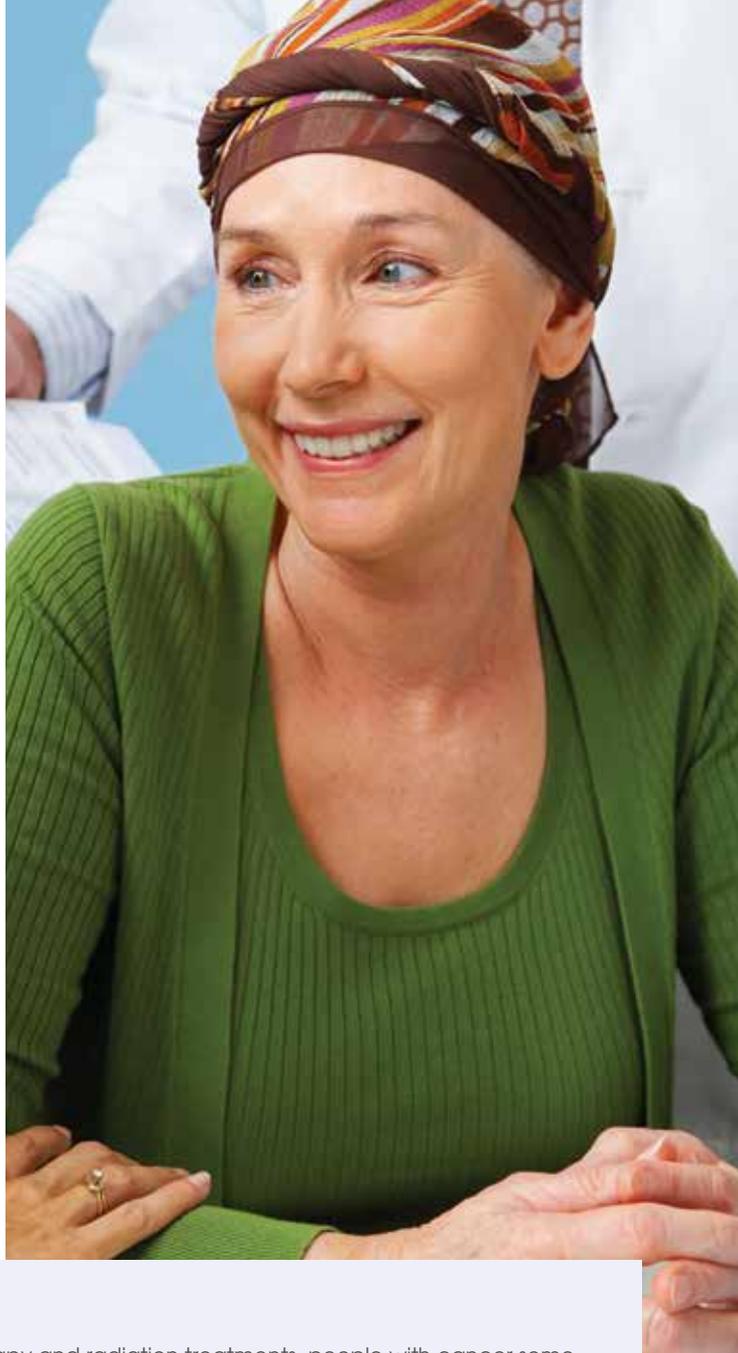
Trying to navigate coverage for medications can be challenging on a good day. It can be particularly bewildering and upsetting when the patient is also trying to cope with a serious illness. Patient assistance programs sometimes offer trained reimbursement specialists to help investigate coverage options. With patient consent, the specialist contacts the public or private drug plan on the patient’s behalf, or via a three-way conference call, to determine what coverage is available and whether additional information may be required for the payer to consider coverage. The reimbursement specialist may also co-ordinate with the patient’s physician to complete the forms necessary for successful adjudication.

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Bridging Treatment Gaps for Cancer Patients

Sanofi's Cancer Patient Assistance Program was developed with cancer patients in mind, by providing a comprehensive support program for some of its specialty medications. The program is bridging gaps to deliver treatment in a timely manner to patients in need. This is made possible through its partnership with Bayshore Specialty Rx Patient Support Services, a network of 40 infusion clinics across Canada that employ trained nurses to administer intravenous or injectable drugs such as Jevtana® and Mozobil®. Both of these Sanofi products are used in the treatment of cancer and require infusion or injection by a trained health-care professional. Patients who have been prescribed these products can access the program, which co-ordinates and funds an infusion or injection scheduled at the nearest Bayshore clinic. Timing is critical for Mozobil® treatment. A trained health-care professional must administer Mozobil® once daily for up to four days, at precise intervals that can take place late at night.

The Sanofi Patient Assistance Program co-ordinates scheduling with the Bayshore clinics, whose hours are flexible and can accommodate late-night appointments, or sends a home-care nurse to administer the injection in the patient's home.



Co-ordinated efforts

In addition to direct therapies for cancer, namely chemotherapy and radiation treatments, people with cancer sometimes have to cope with related conditions such as infection, nausea and bone-related conditions. Oncology-related drugs are often necessary to treat or prevent these conditions, yet patients may find the co-payment required by their private plan to be unaffordable, or cancer agencies may not fund the drug.

Reimbursement case managers employed by Amgen Canada's Victory® patient assistance program work directly with drug access co-ordinators at hospital cancer centres to secure financial assistance for Amgen's oncology-related medications. This support is available to patients with prescriptions for Neulasta® (pegfilgrastim), Neupogen® (filgrastim), XGEVA® (denosumab), Aranesp® (darbepoetin alfa) or Vectibix® (panitumumab). The Victory program also helps educate patients about the conditions and their treatments. A third-party service provider, Adjuvantz®, administers the program.

Drug-access co-ordinators at cancer centres can also sign in to the Victory® program's secure portal to track the progress of their patients enrolled in the program. "The portal saves time for the Victory® reimbursement case managers and me, and frees up both of us to focus on serving the patients who need our services," says Paulette Birmingham, drug-access co-ordinator at the Sudbury Regional Cancer Centre.

Ultimately, the services of co-ordinators like Birmingham and programs like Victory® "relieve some of the stress and confusion that patients face when dealing with a serious disease and frees up the cancer centre health-care team to focus on treating patients," adds Birmingham.

Infusion clinic management

When Health Canada approves a breakthrough complex biologic drug, it can be prescribed by doctors and safely used by Canadian patients; however, it may need to be infused under medical supervision in an infusion clinic, which is traditionally found in a hospital setting. This raises a whole new complexity for private plans, whose group contracts exclude coverage for drugs administered in a hospital. Many insurers consider these to be “insured hospital services” under the Canada Health Act, which means that the hospital should fund them. Private plans may, therefore, decline a claim if the drug is infused in a hospital, whereas it might approve the same claim if the drug is delivered in a private infusion clinic. The situation could be further complicated by the fact that the hospital formulary may not cover the drug either, or at least not yet, because funding decisions for government drug programs tend to take considerably longer than decisions for private plans. To circumvent this potentially distressing turn of events, a patient assistance program may take the form of a network of private infusion clinics for complex biologic drugs.

Trying to navigate coverage can be challenging. Patient assistance programs sometimes offer trained reimbursement specialists to help investigate coverage options.

Home infusions

Some patients requiring infused medications may have mobility issues, live far away from urban centres or face other travel challenges. They may be able to access patient assistance programs that send trained nurses to patients' homes to administer their infusions.

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Comprehensive patient support

Taking a biologic medication that needs to be injected or infused can be an adjustment for people who are used to swallowing a tablet or spreading an ointment. Pharmaceutical companies' patient support programs exist to help ensure patients get access to treatment, understand the importance of adherence to therapy and receive the support they need while on that therapy.

Janssen's BioAdvance® Network is a patient support program that incorporates case management, providing support for patients with prescriptions for their three biologic drugs: REMICADE® (infliximab), STELARA® (ustekinumab) and SIMPONI® (golimumab). These medications are indicated for a number of autoimmune diseases, including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease and ulcerative colitis.

For REMICADE® patients, the BioAdvance® Network offers medically supervised infusions at over 200 access points nationwide. Before each scheduled infusion, an on-site nurse conducts a health assessment that includes a pre-biologic checklist and a recording of vital signs. If the nurse identifies a potential contraindication that may adversely affect the safety or effectiveness of the biologic—for example, the patient is taking an antibiotic—the nurse can follow up with the patient's physician to confirm whether to go ahead with the infusion or reschedule the patient for a later date. The pre-biologic checklist is conducted before the health-care provider mixes or infuses the medication. This ensures that patients receive their infusion when it is appropriate and avoids costs associated with drug wastage if their appointment needs to be rescheduled.

Outside of the clinic setting, BioAdvance® co-ordinators are also available for one-on-one guidance and support as long as the patient is on therapy. Members also have personalized access to BioAdvance.ca on their desktop or mobile device. This site includes relevant information and tools, including email and text reminders, a symptom tracker and a gateway for ordering supplies and other materials that help with treatment.



Help at home

People with hemophilia have blood that does not clot normally. They are at high risk of internal bleeding. Since it's typically an inherited disease, hemophilia treatment usually begins at a very young age and requires regular infusions. In severe patients, treatment is often administered prophylactically, which is the regular infusion of a clotting factor protein to prevent bleeding. Children with severe hemophilia can receive infusion therapy two to three times a week to keep their clotting factor high enough to prevent bleeding.

Twenty-six publicly funded hemophilia treatment centres (HTC) across Canada oversee the treatment for hemophilia patients. Typically, HTC staff initially train parents to infuse their children at home, then eventually train the children to infuse themselves. Not all parents or patients, however, are able to do so. Some patients have physical disabilities linked to the consequences of bleeding events, some can have learning issues, some live in difficult socioeconomic contexts or and some simply live in areas with limited access to HTCs.

For these patients or caregivers with special needs that require additional assistance, the HTC staff can refer them to the Pfizer funded Be Involved program, where patients can receive home-infusion assistance or support linked to the appropriate use of their factor replacement therapy from trained Shoppers Drug Mart Specialty Health Network nurses and staff.

Patient coaching and adherence

Complex and powerful drugs can deliver superb results but may come with unpleasant side effects that can discourage patients from adhering to their treatment. A patient assistance program may include regular follow-up by trained medical staff who encourage continued adherence and counsel patients on how to manage side effects. They may also contact patients prior to a dose to ensure that any necessary medications are ordered or appointments booked (such as for medical tests, physician visits or infusions).

Tests and consultation with health-care professionals

Some medications require consultation with additional medical professionals or certain medical tests before treatment can begin. This can be very time consuming and confusing for patients and delay the onset of treatment. As a result, patient assistance programs help fund, schedule and sequence the appointments, co-ordinate results, consult with the specialist and arrange for treatment, if appropriate. If an illness limits mobility, these programs arrange for lab tests or drug infusions in the patient's home.

Drug distribution and dispensing

A patient assistance program may stipulate that a medication be accessed exclusively through a Canadian drug distributor or wholesaler, home delivery or pharmacy network. This could be a requirement of a risk-management program (see above). Such a program simplifies the timing of deliveries to the home or infusion clinic and can lower drug costs. It also

enables the co-ordination of co-pay assistance for pay-direct drug plans at the point of sale, which might not otherwise be possible through other delivery channels.

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Patient safety

To ensure patient safety, a patient assistance program may co-ordinate the disposal of used needles. It may also offer a telephone line to collect patients' reports of adverse events, which are forwarded to Health Canada.

Closer look at adherence

Once started on their medication, plan members who are taking biologics can turn their focus to understanding and living with their disease. Patient support programs operated or sponsored by the manufacturers of the drug offer various levels of direct support for adherence to treatment and disease management.

For example, AbbVie's Progress Patient Support Program, administered by third-party partner AmerisourceBergen Specialty Canada, includes specially trained health-care professionals who serve as personal wellness case managers for plan members with a prescription for HUMIRA® (adalimumab). With the patient's permission, the wellness case manager contacts the patient at scheduled intervals to assess the progress of treatment and to address any questions or challenges that could affect adherence. The patient's specialist can access the information gathered by the wellness case manager on an ongoing basis so that the specialist can intervene or alter treatment if necessary.

Ongoing education also contributes to adherence. The more patients know about their condition, the more confident they are about their own ability to manage symptoms on a day-to-day basis. This can be particularly true for conditions treated by biologics, which often have unknown causes and no cure. HUMIRA, for example, is indicated for the treatment of a number of autoimmune disorders, including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, Crohn's disease and psoriasis. Autoimmune disorders occur when the immune system mistakenly attacks and destroys substances or tissues that are normally present in the body. In addition to medication, the avoidance of triggers (such as stress) and positive lifestyle behaviours (such as exercise) can help manage or prevent symptoms.



GILENYA* Go program™ by Novartis

^{Pi}GILENYA* (fingolimod) is an oral therapy for the treatment of relapsing-remitting multiple sclerosis (RRMS). GILENYA* is generally recommended in multiple sclerosis (MS) patients who have had an inadequate response to, or are unable to tolerate, one or more therapies for MS.

The Novartis GILENYA* Go program™ is an extensive patient support program that helps both patients and physicians navigate a series of tests to ensure that the right patients are treated with GILENYA*.

The GILENYA* Go program™ supports this process by providing services such as:

1. Electrocardiogram and blood-pressure measurement;
2. Blood work (complete blood count and liver function test);
3. Eye exam (if the patient has diabetes, or a history of eye inflammation or a history of macular edema);
4. Varicella zoster virus antibody status test.

To guide them through the process, patient is provided with personalized nursing support and a GILENYA* passport, which includes a calendar to keep track of their appointments and their test results.

*GILENYA is a registered trademark.

™ Go Program is a trademark.



More Support

How can plan members find out if patient assistance programs are available for their medications?

A number of community-based resources are available to help plan members find out if they're eligible to receive support from patient assistance programs:

- Most of the pharmaceutical-company programs for complex specialty treatments require a physician to refer and enrol patients; therefore, specialists or their nursing or office staff are a great resource for available programs.
- If the plan member has cancer and is being treated in Ontario, most Ontario cancer centres have a full-time oncology drug access navigator whose sole responsibility is to help cancer patients access coverage and other supports from public, private and pharmaceutical-company patient assistance programs. Some hospitals in other provinces are following Ontario's lead and creating oncology drug access navigator roles.
- Pharmacists, especially those who dispense specialty medications, are often aware of different programs and can be a great resource for patients.
- Disease-specific patient support groups or charities can refer patients to a wide variety of support services.
- Contact the medication's pharmaceutical manufacturer to ask if any programs are available. For a list of manufacturers, visit the Canada's Research-Based Pharmaceutical Companies website at canadapharma.org/en/about-rxd/membership.



Road map to coverage

Conditions that require complex or high-cost treatment plans may lead plan members down complicated paths to obtain coverage or financial assistance for therapy—and that can take time away from treatment and recovery. To help make that path smoother, numerous patient groups, health organizations, foundations and government agencies refer those with newly diagnosed conditions to DrugCoverage.ca, an unbiased “first-stop” resource that summarizes what’s available from both private and public reimbursement programs.

The site provides contact information for drug-specific patient assistance programs (if available) and information on private insurance, provincial drug programs, cancer agencies and federal drug plans. It also monitors medication-coverage statuses and provides users with up-to-date coverage information. The site is advertisement-free and operated by Shoppers Drug Mart Inc.

Plan sponsors can share this useful website with their plan members, who can access information by searching via a medication’s brand or generic name. Users will also find plain-language explanations of common drug-plan terminology and processes to help them understand and navigate options for coverage and support throughout the stages of their treatment journey.



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