Patient Assistance Program Primer

Suzanne Lepage
Private Health Plan Strategist
Suzanne Lepage Consulting Inc.
Kitchener, Ontario
Overview

1. What is a Patient Assistance Program?
2. Scenarios/Case Studies
3. Patient Assistance Program Components
4. Value of a Patient Assistance Program
5. INESSS Patient Assistance Programs
6. Resources
What Is a Patient Assistance Program?

“A Patient Assistance Program is a third party program that supports patients to access the medications they need.”
Patient Assistance Programs

Administration

1. In hospital (ODAN)
2. Via health charity or advocacy group
3. In house by pharmaceutical company
4. Pharmaceutical company funded—outsourced to specialized third party supplier (e.g. Adjuvantz, Shoppers Specialty Health, Amerisource Bergen (Innomar), McKesson Specialty)
Scenarios/Case Studies
Scenario 1

- Drug approved by Health Canada
- Infused drug not covered by hospital, provincial plan or cancer agency formulary
- Patients need a way to access medication with medical supervision
- Network of private infusion clinics to allow patients to receive infusions
Scenario 2

- Patients need specialized training or support to receive medication
- Current healthcare system cannot support additional services required
- Program created to provide support that patients and physicians need
Scenario 3

- Physicians and patients want to “sample” a new medication
- New biologic therapies require special handling and refrigeration—cannot be stored in physician’s office or patient’s home.
- Sample “card” provided for physician to give to patient.
Scenario 4

- Coinsurance of 20% on a $30,000 per year drug is $6,000
- Even with private coverage, the coinsurance is a barrier to access
- Program offers financial assistance for patient coinsurance
Patient Assistance Program
Components
# Patient Assistance Program Components

<table>
<thead>
<tr>
<th>Getting Patient Connected with Treatment</th>
<th>Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Financial or co pay assistance</td>
</tr>
<tr>
<td></td>
<td>Bridging</td>
</tr>
<tr>
<td></td>
<td>Compassionate assistance</td>
</tr>
<tr>
<td></td>
<td>Financial support for additional expenses</td>
</tr>
</tbody>
</table>
# Patient Assistance Program Components

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Direct Patient Supports</strong></td>
<td>- Physician concierge&lt;br&gt;- Patient training&lt;br&gt;- Patient disease education&lt;br&gt;- Online tools</td>
</tr>
<tr>
<td><strong>Risk Management/Compliance</strong></td>
<td>- Risk management programs (required by Health Canada)</td>
</tr>
<tr>
<td><strong>Reimbursement Support</strong></td>
<td>- Reimbursement investigation/coordination</td>
</tr>
<tr>
<td><strong>Medication Administration Support</strong></td>
<td>- Infusion clinic management&lt;br&gt;- Home infusions</td>
</tr>
</tbody>
</table>
## Patient Assistance Program Components

<table>
<thead>
<tr>
<th>Success Support</th>
<th>Patient coaching and adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Coordinate appointments with healthcare professionals</td>
</tr>
<tr>
<td></td>
<td>Coordination of tests needed before and after treatment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication Administration</th>
<th>Sequencing treatment steps</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Drug distribution and dispensing</td>
</tr>
<tr>
<td></td>
<td>Patient Safety</td>
</tr>
</tbody>
</table>
Getting Patient Connected With Treatment
### Samples

<p>| Pharmaceutical company representatives provide sample products to physicians to give to patients. |
| For biologic drugs “drug sample cards” given to patients to bring to pharmacy to receive product |
| Allows patient to “try product” to ensure it works for them before they or their private plan has to pay for it. |</p>
<table>
<thead>
<tr>
<th>Bridging</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>• Program may “bridge” the patient with medication or financial assistance while they wait for confirmation of coverage</strong></td>
</tr>
<tr>
<td><strong>• Allows patient to access treatment immediately.</strong></td>
</tr>
<tr>
<td><strong>• Faster access to treatment and provide symptom relief and slow disease progression</strong></td>
</tr>
<tr>
<td>Financial or Co-pay Assistance</td>
</tr>
<tr>
<td>--------------------------------</td>
</tr>
<tr>
<td>• Program provides financial assistance to help pay for a portion of the drug expenses not covered by public or private drug plan.</td>
</tr>
<tr>
<td>• The amount payable may be based on patient based on financial need.</td>
</tr>
<tr>
<td>• There is no “standard”</td>
</tr>
<tr>
<td>• A 10% or 20% coinsurance can be a barrier to access to medications for some patients.</td>
</tr>
<tr>
<td>• Financial assistance may be the only way they can access the medication they need.</td>
</tr>
</tbody>
</table>
### Compassionate Assistance

<p>| • Program may provide free product when no other coverage is available. | • Compassionate assistance may be the only way a patient can access the medication they need. |</p>
<table>
<thead>
<tr>
<th>Financial Support for Additional Expenses</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Program may reimburse patients for travel costs, parking etc. for medical or infusion appointments</td>
</tr>
<tr>
<td>• Can help patients manage growing costs of dealing with their medical condition or whose condition does not allow them to easily travel via transit.</td>
</tr>
</tbody>
</table>
# Patient Assistance Program Components

<table>
<thead>
<tr>
<th>Direct Patient Supports</th>
<th>Physician concierge</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient training</td>
</tr>
<tr>
<td></td>
<td>Patient disease education</td>
</tr>
<tr>
<td></td>
<td>Online tools</td>
</tr>
<tr>
<td>Risk Management/Compliance</td>
<td>Risk management programs (required by Health Canada)</td>
</tr>
<tr>
<td>Reimbursement Support</td>
<td>Reimbursement investigation/coordination</td>
</tr>
<tr>
<td>Medication Administration Support</td>
<td>Infusion clinic management</td>
</tr>
<tr>
<td></td>
<td>Home infusions</td>
</tr>
</tbody>
</table>
Direct Patient Supports
<table>
<thead>
<tr>
<th>Physician Concierge</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Program provides nursing staff to help physician complete paperwork required for reimbursement</td>
</tr>
<tr>
<td>• Frees up physician and office staff time to see patients instead of doing paperwork.</td>
</tr>
</tbody>
</table>
## Patient Training

| • Program provides education and training by phone or in person on dosing, injection, safety, side effects etc. | • Provides support and training to patients and caregivers on how to deliver medication and what to expect from the treatment.  
• Frees up physician and nursing staff time to see patients |
<table>
<thead>
<tr>
<th>Patient Disease Education</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Program provides patient education on their disease</td>
</tr>
<tr>
<td>• Provides disease education that may not readily available in the current health care system.</td>
</tr>
</tbody>
</table>
A Free Resource Kit and Supplies

A resource kit for starting therapy, instruction video/DVD, free puncture-resistant container, travel cooler for temporarily transporting ENBREL, dosing reminder, and more.
<table>
<thead>
<tr>
<th>Online Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Program may offer online patient education or disease or medication tracking tools</td>
</tr>
<tr>
<td>- Gives patient tools to help manage their disease.</td>
</tr>
</tbody>
</table>
### Risk Management Programs

- Minimize known risks
- Identification of new risks in post-market setting.

Health Canada works with:
- Manufacturers
- Health professionals

To develop:
1. Risk communications and education to health professionals, caregivers and patients
2. Risk management tools and interventions
   a. Controlled distribution
   b. Registries

- Patient safety
- Allows access to medication in controlled environment with additional support
The Clozaril Support and Assistance Network (CSAN) is a comprehensive program. Our primary goal is to manage risk by ensuring the appropriate use of Clozaril and that the appropriate hematological monitoring is conducted for each Clozaril patient. CSAN provides the healthcare team with rapid notification (within 24 hours) of adverse hematological trends. Since its inception, CSAN has garnered longer patient experience than any other clozapine monitoring program. By integrating this experience, CSAN has developed a knowledge base that gives it extensive patient expertise and helps to manage the risk of agranulocytosis over time.
START: YOUR FIRST-DOSE EXPERIENCE

At the beginning of treatment, GILENYA® causes the heart rate to slow down, and can cause an irregular heartbeat, especially after the first dose.

For this reason, you will receive your first dose at a GILENYA® First-dose Observation Centre, where your heart rate and blood pressure will be monitored hourly, for at least 6 hours, to see how you tolerate the medication (your doctor may decide to observe you in his/her own clinic).

You will also be required to have an ECG to check the health of your heart before starting GILENYA® – and a second ECG 6 hours after your first dose.

In case of an abnormal ECG recording or slow heart rate after 6 hours, you will need to be observed longer, possibly overnight, in a health care facility.

During your time at the GILENYA® First-dose Observation Centre, you will be surrounded by supportive health care staff who are available to answer any questions you have. The time you spend at the Centre is time for you. You can choose to take it easy and read a book or magazine, play games, or you may wish to bring your laptop and catch up on work.

You may also consider bringing a family member or friend to the GILENYA® First-dose Observation Centre with you, if the Centre permits.
Reimbursement Support
<table>
<thead>
<tr>
<th>Reimbursement Investigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Program helps the patient by investigating what private and public drug coverage is available and helps to complete any necessary paperwork required.</td>
</tr>
<tr>
<td>• Helps patient navigate the complexity of private and public coverage available to them.</td>
</tr>
<tr>
<td>• Insurance coverage can be bewildering at the best of times—highly valued in a time where the patient is ill and family is likely very stressed.</td>
</tr>
</tbody>
</table>
Medication Administration Support
## Infusion Clinic Management

<table>
<thead>
<tr>
<th>• Program invests in private infusion clinics to deliver drug to patients.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Program provides a free medically supervised infusion clinic where patients can receive drugs approved by Health Canada when no other options exist.</td>
</tr>
<tr>
<td>Home Infusions</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td><strong>• Program provides nursing support to deliver drug infusions in patient’s home.</strong></td>
</tr>
<tr>
<td><strong>• Allows patients to receive treatment in the comfort of their home.</strong></td>
</tr>
<tr>
<td><strong>• Very helpful when the patient lacks mobility.</strong></td>
</tr>
</tbody>
</table>
# Patient Assistance Program Components

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Success Support</strong></td>
<td>Patient coaching and adherence</td>
</tr>
<tr>
<td></td>
<td>Coordinate appointments with healthcare professionals</td>
</tr>
<tr>
<td></td>
<td>Coordination of tests needed before and after treatment</td>
</tr>
<tr>
<td><strong>Medication Administration</strong></td>
<td>Sequencing treatment steps</td>
</tr>
<tr>
<td></td>
<td>Drug distribution and dispensing</td>
</tr>
<tr>
<td></td>
<td>Patient Safety</td>
</tr>
</tbody>
</table>
Success Support
# Patient Coaching and Adherence

| |  
|---|---|
| **• Program staff follow up with patient after medication is taken to provide counsel and support.** | **• Helps encourage adherence/compliance after medication is started—especially when there are known negative side effects** |
**Coordinate Appointments With Health Care Professionals**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Program staff coordinate appointments with necessary healthcare professionals that need to be seen prior to after treatment.</td>
<td>• Helps patient with timely access to additional health care providers needed as part of the treatment</td>
</tr>
</tbody>
</table>
1 ASSESS: PRE-FIRST-DOSE EVALUATIONS

Prior to starting GILENYA treatment, your doctor will review your current medical history and medications, and will request certain tests such as:

- **Varicella zoster virus (VZV) antibody status** (if you have no history of chickenpox or have not had the chickenpox vaccine)
- **Electrocardiogram (ECG) and blood pressure (BP) measurement**
- **Blood work** (complete blood count, liver function test)
- **Eye exam** (if you have diabetes, or a history of uveitis or macular edema)

If your doctor has decided you are a good candidate for GILENYA®, you can be enrolled in the GILENYA® Go program™ and will receive a patient starter kit in the mail. The kit contains useful items to help orient you on your new MS treatment, including a patient information booklet, and membership wallet card with our support number and email: 1-855-PILL-4MS (1-855-745-5467, Mon–Fri 08:00–24:00, Sat 09:00–17:00 EST), gilenya.go@novartis.com.

The GILENYA® Go program™ is there to help you every step of the way with your therapy, providing extensive support. Upon enrollment, a GILENYA® Go program™ nurse navigator follows up with a welcome call within 24 hours, and answers any questions you may have.

Your nurse navigator will also arrange for you to speak with a reimbursement specialist. Our
Coordinate Tests

- Program staff coordinate tests needed before and after drug treatment
- Helps patient with timely access to tests needed as part of treatment.
Agranulocytosis is a condition in which the body fails to produce the white blood cells that it needs to fight infections. Detecting the warning signs of this blood condition at an early stage allows it to be prevented or reversed in most cases. That’s why regular monitoring and verification of blood counts is so important.
Blood Monitoring

Agranulocytosis is a condition in which the body fails to produce the white blood cells that it needs to fight infections. Detecting the warning signs of this blood condition at an early stage allows it to be prevented or reversed in most cases. That’s why regular monitoring and verification of blood counts is so important.

Learn More...
<table>
<thead>
<tr>
<th>Sequencing Treatment Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Program sequences treatment steps for patient: Tests, Doctors, Training, Drug Delivery, Infusion Clinic Disease Education, Tests, Home Visits, Follow Up, Side Effect Management etc</td>
</tr>
<tr>
<td>• Ensures appropriate sequencing of treatment which can often be confusing and time consuming.</td>
</tr>
</tbody>
</table>
## Drug Distribution and Dispensing

| Program may offer                                                                 |  
|---------------------------------------------------------------------------------|---|
| • Canadian distributor and wholesaler for pharmaceutical company                 |   
| • Preferred home delivery or pharmacy network.                                 |   

| May offer                                                                         |  
|---------------------------------------------------------------------------------|---|
| • Simplifies timing of home/infusion clinic delivery of medication.              |   
| • May lower drug cost                                                            |   
| • Can coordinate co-pay assistance at the point of sale for pay direct drug plans |   
| • May be required for Risk Management Program                                   |   

5D-48
<table>
<thead>
<tr>
<th>Patient Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Program may coordinate disposal of used needles and respond to adverse events and report to Health Canada</td>
</tr>
<tr>
<td>• Ensures Patient Safety</td>
</tr>
</tbody>
</table>
Value of Patient Assistance Programs
Adherence Challenges

Analysis of claimants living with one or more chronic conditions:

• **71% did not fill their prescriptions** at the correct intervals in order to receive the maximum benefits from their medications

• **23% discontinued their therapy** after first filling of the prescription

• **4% discontinued their therapy** too soon after initially being adherent

• Adherent patients had **17% fewer STD and 15% fewer LTD** claims

Value of Patient Assistance Program

- 86% of respondents had improvement in ability to work at their job
- 58% of respondents reported that program helped them miss fewer days of work
- Number of respondents reporting disability claims decreased by 76.8%
- 55% said program helped remind them to take their medication on time

Value of Patient Assistance Program

- 82% of individuals who participated in a Patient Assistance Program (PAP) for a biologic drug remained on the treatment one year after initiation

- Equivalent to higher end of recent review of other studies on adherence rates for biologic treatments in similar patient population
  1. 12 month adherence values ranged from 42% to 89%
  2. One year adherence rates ranged from 69% to 87%


5D-53
INESSS—PATIENT ASSISTANCE PROGRAMS
INESSS Patient Assistance Programs

• Access to infliximab administration sites throughout Quebec is crucial.

• The drug is administered intravenously and requires careful monitoring because of the serious adverse effects that can be caused by its administration.

• Since infliximab began being used for ambulatory care, private infusion clinics financed by the manufacturer of Remicade have been set up.

• The manufacturer of Inflectra has committed to emulating this care model, which is essential to the safe administration of the medication, but currently, fewer clinics have been set up than the number in the network developed by the sponsor of Remicade.
The development of a network of infusion clinics financed by the pharmaceutical industry is not without risk for the public healthcare system.

Maintaining a private network of this kind is closely linked to the sale of the medication which gave rise to its establishment.

If one of the products were to lose substantial market share, there is some apprehension that the number of clinics would decrease, thereby curtailing access to the administration of certain products on the List of Medications.

It is unlikely that the public system will be able to respond to an increased demand for infusions in the short term.

...the availability of a privately funded infusion service was one of the factors considered in the economic analysis of applications for the listing of intravenous biologic drugs.
Resources
How Do Patients Find Out About Programs?

1. Physician/specialist or nurse/office staff
2. Oncology Drug Access Navigator in Cancer Centres
3. Pharmacist
4. Contact patient support groups or charities
5. Contact the pharmaceutical company
6. DRUGCOVERAGE.CA
Medication Search Results

**Neupogen**

**Generic name:** Filgrastim

**Manufactured by:** AMGEN Canada Inc.

**DINs in Canada:** 01888017

A summary of national coverage for Neupogen is below. Healthcare professionals may click here to obtain private insurance coverage information, clinical eligibility criteria, special authorization forms and instructions for submitting prior / special authorization requests.

**Patient Assistance Program**

**Victory Program** - please call 1-888-766-4717 for more information.

**Coverage/Reimbursement by Private Insurance Plans in Canada**

Please contact the private insurance company that provides your prescription drug benefits, or the plan administrator (where the plan member works) to determine if Neupogen is covered by your drug plan.

**Coverage by Canadian Provincial / Territorial Programs**

<table>
<thead>
<tr>
<th>Province</th>
<th>Eligibility Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alberta</strong></td>
<td>Covered according to eligibility criteria established by the Alberta Health and Wellness Special Authorization mechanism.</td>
</tr>
<tr>
<td><strong>British Columbia</strong></td>
<td>The B.C. Cancer Agency provides coverage according to eligibility criteria (as listed in the BCCA Drug Benefit List).</td>
</tr>
<tr>
<td><strong>Manitoba</strong></td>
<td>Covered according to eligibility criteria established by Manitoba Pharmacare's Exception Drug Status (EDS) mechanism.</td>
</tr>
</tbody>
</table>
Patient Assistance
PROGRAM PRIMER

The private benefits plan sponsor’s guide to the patient assistance program
Questions and Discussion