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June Seamans

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THE SCOOP

Viatical settlements providing terminally ill millions in financial relief

Considering the private financial options available to persons living with HIV today, the "living" benefits of life insurance through viatical settlements has surpassed all options in benefit amount and speed of payment. A viatical settlement is when a person with a life threatening illness sells his/her existing life insurance policy for up to 85% of the policy's face value. Viatical settlements are paid by, yes, viatical settlements companies. Over 4, 000 people living with HIV, AIDS, cancer and other life threatening illness applied for viatical settlements in 1994 and this number is expected to double in 1995. In 1994 alone, over 300 million dollars in life insurance coverage was converted into cash for viators (the person selling his/her policy). Unfortunately, not everyone is luck enough to have life insurance, but for those of us who do have some sort of group, term, or whole life insurance, a viatical settlement can make a world of difference.

Today, more people in the later stages of AIDS are applying for ADB's (accelerated death benefits) than ever before. ADB's are paid by life insurance companies. A common payment is 50% of the face value and the other 50% remains for the current beneficiary or, in most cases, can be viaticated. ADBs are more restrictive that viatical settlements because the policy holder has to be within a 6-12 month life expectancy whereas people who are HIV asymptomatic can qualify for a viatical settlement with as many as 1000 T Cells. Also, ADBs are currently included on only about 5% of all life insurance policies, but are becoming increasingly available.

Generally there are 2 types of viatical settlement companies: funding companies and "brokers". More specifically and in response to the great need of viatical services, 2 types of "brokers" have emerged; "brokers" who represent funding companies and "brokers" who represent the viator, more commonly known as "viator advocates". The most common misconception is that a viator will receive a higher settlement by self-negotiating their settlement with a funding company. According to The Medical Escrow Society, the nations largest viatical settlement service organization and first viator advocate, reports that the highest settlements in the industry were secured by experienced viator advocates or "brokers". This type of "broker" has a fiduciary (relating to trust) relationship with the viator and, by creating competition between as many reputable funding companies as possible, they are responsible for negotiating and securing the highest cash settlements. Moreover, the older and larger brokers like The Medical Escrow Society are able to get funding companies to pay these higher than market settlements due to the leverage generated from their large volume of policies and viators being represented.

Be aware that funding companies are in the business of buying life insurance policies for a return on their investment. Their relationship with the viator implies and inherent conflict of interested. How can a funding company act in their own best interest and in the best interest of the viator simultaneously? They cannot help but hope that the viator will accept the first or second offer that is given. Many funding companies have recently gone as far as employing "financial planners" who are well known in the community to help them establish trust and bridge this inherent conflict. A good financial planner will recommend at least 2 or 3 viatical companies including viator advocate type "brokers". If your " financial planner" does not, there is a good chance he is a dedicated agent or employee of a single funding company.

"Brokers" typically charge a fee only to the funding company. This fee is not subtracted from the settlement amount, but comes from the funding company's operating expenses. This fee includes costs that the funding company would normally incur to complete the transaction without the broker such as gathering medical records, insurance verification, legal paperwork etc. However, many young and captive brokers do not provide this services and are more like middleman who bid the policies to only 1-2 funding companies. This type of broker as well as funding companies who occasionally broker to other funding companies incur additional expenses for the ultimate buyer of advocate type "broker" or even dealt with the funding companies on his/her own.

Our thanks to The Medical Escrow Society , Tavares, FL for allowing us to reprint this information. For more information please contact Javier Martinez at The Medical Escrow Society at 1-800-422-1314.

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There's more to life than AZT alone
An Introduction to Protease Inhibitors

What is a Protease Inhibitor?

Protease (Pro-tee-ace) *inhibitors* are a new group of drugs. They fight HIV directly. Some are approved and some are still experimental. Believe it or not, there are about 20 different kinds of protease inhibitors.They have different strengths. Some are close to approval. Others are just getting studied.

How do you do the things you do?

In order for HIV to cause damage, it needs to reproduce over and over. This takes many steps. The enzyme *protease* is one important step. HIV needs this enzyme so it can make copies of itself. These drugs stop the protease enzyme.

Are these drugs like AZT?

NO. AZT, ddi, ddc,d4t and 3tc are a different family of drugs. They are called *nucleoside analogues.* They work against HIV by trying to stop a different enzyme-one called *reverse transcriptase.* AZT-like drugs work well in some people, but not in everyone.

Why not? First, these drugs are not specific. They may attack lots of white blood cells, even one that don't have HIV in them. Second, these drugs can cause serious side effects. Third, they stop working in most people in 6-12 months.

What else? AZT-like drugs are not as strong against HIV as some of the protease drugs. Also, they only protect white blood cells that are not infected. They do not fight the HIV that's already in the cell. Protease inhibitors can enter infected cells and stop HIV from reproducing.

So far, protease inhibitors seem much safer than AZT and the other nucleoside analogues. They are so specific that they don't hurt your bone morrow, or other white blood cells, but there is *no* data on long-term safety.

Are there any problems with protease inhibitors?

Yes. With all drugs that fight HIV, like AZT or 3TC or protease inhibitors, *resistance* can be a big problem. *Resistance* happens when HIV learns to keep growing in spite of a drug. When HIV is *resistant* to a drug, that drug can no longer fight HIV.

If your HIV learns to get around AZT, you can (if you want), switch to ddi. This is probably not true with protease inhibitors. Taking one protease drug might change the HIV in your body so that no other protease will work for you. This is called *cross resistance.* **Unfortunately, it seems that all the protease inhibitors can cause cross resistance, although it might *not* happen on an individual basis.**

Can resistance be stopped?

The HIV virus is very smart and can learn to resist a lot of drugs. However, we hope that combining drugs (taking more than one anti-HIV drug at a time) will confuse HIV. When drugs are combined, HIV has a harder time learning to get around the drugs. And if a combination doesn't stop resistance, it might slow it down.

Some doctors feel that protease drugs should be taken with other anti-HIV drugs like AZT and 3TC to slow down resistance. We have no idea right now if this will work. Hopefully, trials studying this combination will let us know.

Are there any side effects from taking protease inhibitors?

Like so many things that appear to help us fight HIV, there are side effects with protease inhibitors.

First, you will have to take a lot of these drugs for them to work. The body can't absorb protease very well. Taking a high amount of any drug can often mean trouble for your liver, kidneys, and stomach. The more drug you have to take, the harder your liver needs to work to break it down, causing problems.

Second, there are many drugs you will not be able to use depending on which protease inhibitors you decide to take. These include Rifampin, Rifabutin, Prozac, and Seldane. Side effects reported are headaches, shot term diarrhea, upset stomach, and some rashes, more rarely kidney stones and blood pressure problems.

Okay, so which protease inhibitors should I keep my eyes on?

There are three protease drugs that are approved. We still do not know if taking these drugs will keep you from getting sick in the long run.

Invirse (Saquinavir) is sold by Hoffman-LaRoache. This drug is the weakest, working only with other antivirals like AZT on a good day. But it causes weaker cross resistance than Norvir or Crixivan.

Norvir(Ritonavir) is made by Abbott. Its is absorbed more easily. It appears to be very strong and was approved in February by the FDA for people with advanced HIV disease. It will continue to be in trials with different combinations of necleosides and protease inhibitors.

Crixivan (Indinavir) is made by Merck. This is also a very strong drug. It was also approved in February by the FDA , has fewer side effects and may have longer lasting antiviral effect than Ritonavir. **There is a limited supply of Crixivan, so the sooner you sign up the better.** (The PWA health group has a detailed sheet on how to access this drug. Call 212-255-0520).

Where can I get more info?

Clinical trials with protease inhibitors

- AIDS Treatment Data Network 1-800-734-7104
- NIH AIDS/HIV trials hotline: 1-800-TRIALS-A
- PWA Health Group, 150 West 26th Street, Suite 201, NY NY 10001. Phone 212-255-0520

Articles about protease inhibitors

- AIDS Treatment Data Network 1-800-734-7104
- Being Alive 1-213-667-3262
- GMHC 1-212-337-3505
- National Minority AIDS Council *Protease Inhibitors: How to use them the right way (also available in Spanish)* 1-202-483-6622
- Positively Aware 1-312-472-6397
- Project Inform 1-800-822-7422
- PWA Health Group 1-212-255-0520

Patient Assistance Programs/Hotlines

- Statlanders Crixivan hotline 1-800-927-8888 (8:30am-9pm EST) Fax: 1-800-238-1549
- Abbott's Norvir (ritonvir) Patient Assistance Program 1-800-293-4393

Protease Inhibitors At-A-Glance

May 1996	Crixivan (Indinavir/Merck)	Norvir (Ritonavir/Abbott)	Invirase (Saquinavir/Roche)
What is the correct dose?	Four 200mg (or two 400mg) capsules every 8 hours on an empty stomach. [You can take it with a piece of dry toast and black coffee; but no fat at all].	Six 100mg capsules every 12 hours with food. Talk to your doctor about starting at a lower dose to avoid side effects. **Note: This medicine contains alcohol.**	Roach says to take three 200mg capsules 3 times a day (1800mg), but some doctors suggest 3600mg or even 7200mg a day (3-18 pills a day)
How should I store it?	Keep in cool, dry place.	Keep in your fridge.	Keep at room temperature.
What is the effect on disease progression?	Unknown. There is clinical trial in progress to determine effect on disease progression. The only data so far is on viral load and T-cells, not on preventing illness.	In a big trial, people with less than 100 T-cells took Norvir & whatever combination of antivirals they wanted. People who took Norvir had half as many OIs & half as many people died. There is no info on people who have less advanced HIV infection.	Unknown. There is currently 1 trial open studying a new formulation of Invirase in 600 people with less than 500 T-cells.
What is the effect on the virus?	The amount of HIV in blood can be reduced by 100 times (e.g. by 100,000 to 1,000 copies). This has been seen in the lymph nodes too, in a few people studied. We are told that about 20% of the drug is absorbed into the brain.	The amount of HIV in blood is reduced by up to 100 times on average. No info on how it works in lymph nodes, and only 1 % of Norvir gets into your brain.	The amount of HIV in blood is reduced by up to 55% when drug is taken with AZT or ddc. It is not known how combinations affect viral load in the blood, lymph, or brain. ***The drug is only for use in combinations.***
How long does the antiviral effect last?	In small numbers of patients the effect on the virus lasts 6 months to 1 year in 40-60% of people who take Crixivan alone. Although the effect seams steady, we don't know how long or how strongly the effects last.	Unknown. No info on people who have taken Norvir for longer than 4 months. In advanced patients, the antiviral effect seems to decrease between the 2nd week & 4th month of therapy.	If Invirse is taken alone the effect is less than AZT taken alone and lasts for about 6 months longer. It lasts longer if Invirase is taken in a combination.
What is the effect on CD4 counts (T-cells)?	On average, CD4 counts increased by about 100 and seem to stay up for 6 months to a year, in most of the few patients who have taken the drug for that long.	In most studies, CD4 counts increase between 30 and 60 T-cells, but the follow up is very short.	On an average, Cd4 counts increase 40 to 70 T-cells within the first few weeks of treatment, but taper off between 4 to 6 months, even in combination.
Can it be used with other anti-HIV drugs?	Yes. Combinations with AZT & 3TC, and AZT&ddI, were well tolerated. In fact, early data suggests that combination therapy may delay resistance. Note: It's recommended that ddI & Crixivan be taken at different times of the day, and both on an empty stomach. HELLO!!! When do we eat????	Poorly tolerated... 2 out of 5 people who took Norvir & AZT dropped out of the study. 1of 3 who took Norvir, AZT & ddC dropped out. In fact, because it's so hard on your stomach, its recommended that you start with 2 weeks of Norvir alone and /or start at a lower dose to get use to it... it's supposed to get better.	YES. Some felt nauseous, weak, and had stomach pain when they took Invirase and AZT or ddC, but the combination of ddC & Saquinavir extends people's lives compared to monotherapy. Resistance is delayed with combination anitviral therapy. There is a clinical combining Invirase & Norvir; but we have NO idea if this is safe at all.

Protease Inhibitors At-A-Glance

May 1996	Crixivan (Indinavir/Merck)	Norvir (Ritonavir/Abbott)	Invirase (Saquinavir/Roche)
Can it be used with other types of drugs?	Don't take: rifampin, **Hismanal** or **Seldane, Halcion, Propulsid, Versed,** antacids. Change dose: **Nizoral, Mycobutin** and rifampin. All these medicines get processed by the liver and the amount of Crixivan you absorb will change if you take these as usually prescribed. **Check with your pharmacist before taking anything, even over-the-counter, with a protease inhibitor.**	Don't take: **Luminal** or **Solfoton, Tegretol, Invirase,** antacids, dex-amethasone, **Flagyl, Dilantin,** rifampin, tinidazxole, **Mycobutin.** Change dose: **Biaxin, Norpramin, Antabuse,** ketaconozole, **contraceptives** and broncodilators. **Tell your doctors you're taking Norvir if they prescribe any drug to you. The list provided by Abbott is not complete. Hey! Anything can happen!!!**	Don't take: rifampin, **Mycobutin Luminal** or **Solfoton, Dilantin,** dex-amethasone, **Tegretol, Hismanal** and **Seldane.** Check with your doctors for antacids, heart meds, asthma meds, antifungals, sedatives, pain killers, antibiotics, and **Dapsone.** Invirase is poorly absorbed by your body and a lot of drugs make the absorption even worse, so **check it out with your doctor!!!**
What are the side effects?	Crixivan causes low back pain due to kidney stones in 2-3% of patients. You can reduce your chances of this by drinking lots of extra water- like 8 to 10 glasses a day. Bilirubin levels go up in the blood, but this doesn't seem to cause any problems.	Lots of side effects: nausea, vomiting, tingly lips, gas & diarrhea, which have forced people to stop taking the drug. Up to 25% of patients using Norvir alone stopped, and 38% of people stopped who took it in combo. We have no data on the new formulation that they claim is gentler- but people report it's no different. Norvir makes triglyceride levels (a type of fat) go up, but we don't know if this necessarily causes any problems.	Of course, a few people have strange(and dangerous) reactions to Invirase, but overall it's easier on your system than AZT. Most of the side effects have to due with the fact that you have to take so much Invirase to have any get into your system. Roche is studying a new formulation that may be easier to absorb. This should reduce stomach side effects.
How important is it to take the drug exactly as prescribed?	**VERY IMPORTANT!!!!!!!! Missing doses or taking lower doses might result in your virus becoming resistant to Crixivan and all other protease inhibitors** (*called cross resistance*). The drug however, was well tolerated in clinical trials. More than 90% of patients took this drug, even in combination, without stopping.	**VERY IMPORTANT!!!! Missing doses or taking lower doses might result in your virus becoming resistant to Norvir and all other protease inhibitors (cross resistance).** The drug was not well tolerated in clinical trials. 25% of patients stopped taking the drug when used alone and more than 1 out of 3 people stopped Norvir in combination trials. **This is a very important consideration if you decide to take Norvir because of the potential for cross resistance.**	**VERY IMPORTANT!!!! Missing doses or taking lower doses increases the chances of HIV becoming resistant to Invirase.** It seems that most resistance caused by Inviraseis different than resistance cause by Crixivan & Norvir. If Invirase stops working for you, the other protease inhibitors will still be an option, most likely.
Where is the drug available?	*Only* through Stadtlanders, a mail order pharmacy: 1-800-927-8888. Merck's patient assistance program: 1-800-850-3430.	In most pharmacies today. Patient assistance: 1-800-293-4393.	Drugstores all over the U.S. Patient assistance: 1-800-282-7780.
How much does this drug cost?	Less than a ton. Merck sells Crixivan for $4,380.00 a year, yet Stadtlanders charges individuals $6,022.00, a 37% markup!!! Insurance companies get it for less!!!	A ton, or about $8,000.00 per year.	A veritable bargain at $7,600.00 a year.

Protease Uninhibited

What is the best way to use protease inhibitors?

To make sure your body gets the full benefit from protease inhibitors you must be aware of the things you can do to help your body better absorb these drugs.

- Take Invirase (Saquinavir) within 2 hours of a full meal or a substantial snack.
- Take Norvir (Ritonavir) with a full meal that is high in fat and protein.
- Take Crixivan (Indinavir) on an empty stomach, 1 hour before or 2 hours after meals, with a large glass of water. Drink at least 48oz of liquids daily to maintain hydration. You can take your Crixivan with a light meal, low in fat, if you need to. A light meal might be plain toast with juice or skim milk.

Excerpted from Protease Inhibitors: How to use them the right way, National Minority AIDS Council, Phone 202-483-6622. (Also available in Spanish)

Some things to keep in mind about Protease Inhibitors

1. **Not all protease drugs are alike.** Their effectiveness, the kinds of resistance they cause, side effects, how well they work in combination with other drugs, and what kinds of antibiotics, anti-virals, antihistamines and birth control you can use at the same time are different with each drug.

2. **Two of these drugs,** Crixivan and Ritonavir **are the strongest anti HIV drugs to date.**

3. **Taking protease drugs with other anti-virals,** like AZT/3TC, ddi, d4T, etc., may make them stronger and help the effect last much longer than just taking 1 protease alone

4. **There is a lot of variation in how people respond to these drugs.** In trials, some people have had fantastic T-cell increases and viral load drops. Other people had very little response.

5. **Taking a protease drug requires a different kind of commitment from you than any previous anti-HIV drug.** Be clear with yourself before starting that you can really commit to the drug as prescribed, each and every time period. WHY? Because antivirals can only work if HIV is not resistant to them. Avoiding resistance for as long as possible is the key to getting the most of the protease drugs. If you skip doses, even a few times, or less than prescribed your HIV may become resistant. In early protease trials, people how took lower doses developed many different kinds of HIV resistance, and now none of the protease drugs will work for them.

6. **Taking one can make you resistant to the others.** Saquinavir can cause a partial resistance, but in some cases, full cross resistance. Taking Crixivan or Ritonavir will make you resistant to all other protease inhibitors. This is called cross resistance. It means you can probably only benefit from one of the powerful protease drugs. Once your HIV gets resistant to one you choose, no other protease drugs will work for you.

So, it's worth taking the time to figure out your protease strategy.

Check what drugs you take with each on them, how often you take them, and what side effects you might expect. (See chart on pages 4-5) Consider getting a viral load test to measure what HIV is up to in your blood. Choose which drug(s) you want to try, if or what other anti-virals you want to take at the same time, and consider whether you can really commit to following you strategy 100%.

How can you tell if your HIV is becoming resistant to a protease drug (or 3TC/AZT or DDI, etc.)?

By taking a viral load test. If your numbers are high, say 300,000, and you start a drug, your numbers should fall in a month. If they stay the same, or go up, then the drugs aren't working very well for you. It's more confusing if your viral load is low. Is it the drug, or your immune system, or both, keeping your virus low? You may talk to your doctors-keep watching your viral load. In time we hope to better understand of how to use the viral load test.

Some BIG unresolved questions

- What is the best drug combination to keep HIV and resistance low?
- What are the long term safety issues?
- Lots of people agree that PWA's with high viral loads and symptoms, who have takes AZT and other drugs for years, might want to try protease. What about everyone else?
- What if your viral load is high, but you have not symptoms? Many argue that keeping HIV as low as possible is the key to survival.

Others worry about getting strong resistance, before having any symptoms.

- What if viral load is very low-under 10,000? Taken combo anti-virals may keep it low, or maybe your immune system would do that anyway. Maybe a strong protease combo will kick you into some kind of remission, with no progression for years. Or maybe it will not change much, except to cause your HIV to become so resistant that you can't get any benefit from anti-virals if your T-cells fall later. <u>We have no idea.</u>

What can you can do to prevent the development or resistance?

- Take protease inhibitors in combination with 1 or 2 other kinds of anti-HIV drugs. Don't do combination therapy with 2 protease inhibitors: we still don't have enough information to support the use of 2 protease inhibitors at the same time. Figure out with your doctor, or by yourself with the help of treatment advocates, which combination works better for you.
- Take full dose prescribed by you doctor everyday.
- **If the side effects are intolerable** don't reduce the dose. Don't skip a dose. And don't take it everyother day. The best thing to do is to stop the drug altogether. Talk to your doctor about starting again.
- **Don't take "DRUG HOLIDAYS".** You must not skip a dose. If you want the full benefit, you have to be good and keep taking the drug everyday. Remember once you have resistance to 1 of the protease inhibitors, you may not benefit from the others.
- **If you miss a dose by more than 3-4 hours wait until the next scheduled dose.** Don't double the next dose. But if you miss a dose by less than 2 hours go ahead and take the next dose at the regular time.

Excerpted from Protease Inhibitors: How to use them the right way, National Minority AIDS Council, 202-483-6622. (Also available in Spanish)

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