

Aids Action Now
Proposed Reform of Ontario Drugs Benefit Formulary

No one would argue that enormous deficiencies exist in the current Ontario Drugs Benefit Formulary. Aids Action Now has compiled the following information in consultation with front-line physicians.

It is important to stress that this is not a 'wish list' and nor are these radical treatment demands, but merely the drugs needed to adequately treat people living with HIV and AIDS (PHA's) in 1995. We must also stress that the inclusion of these products is the beginning of a process, not the end. The Facilitated Access List is the vehicle to continually introduce new treatments in this rapidly evolving field.

Given the ease of use of drugs on this list, and the control its usage provides the government, we propose that it be the mechanism to include the products discussed in this document. Physicians cannot continue to use the cumbersome Section 8 process. For this to work, we also require that the list of physicians with access to the Facilitated Access List be updated monthly.

Category #1: Approved Drugs Requiring Immediate Inclusion

Atavoquone (Mepron)

Atavoquone is an anti-PCP drug that is well documented in the treatment of mild to moderate PCP. It is used in the sulpha-allergic patient as an alternative to the much more expensive Intravenous Pentamidine treatment. It is also being used as a prophylactic agent.

Clarithromycin (Biaxin)

Clarithromycin has become the gold-standard in the treatment of Mycobacterium Avium Complex. No credible MAC treatment regime fails to include Clarithromycin. It is also very effective in MAC prophylaxis for PHA's intolerant to Rifabutin.

Itraconazole (Sporanox)

Itraconazole is used to treat yeast and fungal infections in people with advanced immune suppression. Unlike all other approved drugs in this antifungal category, Itraconazole is effective against eosinophilic folliculitis.

Topical Clindamycin (Dalacin)

Eosinophilic folliculitis is a chronic condition characterized by severely pruritic inflammatory vesicles. Clindamycin So 1st and Itraconazole are the only effective treatments.

Decadurabolin

Decadurabolin is an anabolic steroid used for Wasting Syndrome. Wasting Syndrome is a CDC-defined AIDS-presenting illness, which is responsible for 10-15% of AIDS deaths. Decadurabolin is safe and effective, its use resulting in increased lean body mass (LBM), which in turn has been shown to correlate with increased health. The only anabolic compound currently on ODB is Durabolin, however, this agent is far less effective and is being discontinued by Organon. Megace is a weight-gaining drug and it is on the ODB, but in addition to a high incidence of side effects, Megace causes an increase in fatty tissue, which is not correlated with health. Decadurabolin produces the same type of beneficial increases in lean body mass as rHGH, but at a fraction of the cost.

Potassium Tablets/Capsules (e.g., Slow K)

Although liquid potassium supplements are available on ODB, they are inappropriate for most PHA's. Potassium loss is usually due to conditions or drugs which cause nausea and vomiting. Liquid agents are unpalatable and their use often results in an exacerbation of these symptoms. Potassium in an encapsulated form is a more practical agent in this population.

'Magic Mouthwash' (Benadryl Elixar 125ml
Dexamethasone Liquid 22.5ml
Nystatin Susp. 30ml
Tetracycline (125mg/5ml) 30ml)

This is a very commonly used preparation for the treatment of aphthous ulcer.

Atarax/Benadryl/Reactine

As HIV progresses, dermatologic conditions develop. These are often characterized by severe and chronic pruritis. Although not life-threatening, these conditions cause morbidity and physician visits. As well as their anti pruritic properties, these antihistamines can be used to maintain people with borderline sulpha-allergies on Septra.

Paromycin (Humatin)

Cryptosporidial infections are one of the more dreadful of the opportunistic infections. This condition results in severe diarrhea, leading to death by dehydration and starvation. In the last few years we have been able to alleviate the suffering caused by this parasite with Paromycin. We have accessed this drug via the Emergency Drug Release Program (EDRP). The drug was shown to be effective and was licensed by HPB. This governmental approval of its efficacy has resulted in lost access via the EDRP.

Gravol

The number of HIV-related conditions that cause nausea is rivaled only by the number of HIV-related medications that do the same. Gravol's proven efficacy and tolerability, make this low-cost product essential in both oral and parental forms.

Septra Desensitization Dilution Fees

Due to its superior efficacy and low cost, Septra is the treatment of choice for PCP prophylaxis. To try to combat the 30% incidence of Septra allergies desensitization protocols have been developed. These require many highly diluted Septra solutions to be prepared. There is confusion at the pharmacies over payment of the preparation fees. Some bill it to the government, others charge an additional fee to the purchaser. Clear instructions must be sent to pharmacists, assuring them of payment for the additional expenses incurred to make these protocols.

Azithromycin 250mg Tablets

This macrolide antibiotic is used frequently by PHA's due to its tolerability and its efficacy against both typical and atypical respiratory pathogens. We also know that as the immune system weakens new drug allergies emerge, but Azithromycin seldom causes an allergic reaction, making it very useful in the multi antibiotic allergic patient.

Azithromycin is also useful against AIDS-related opportunistic infections. Its use in treating toxoplasmosis is particularly impressive, but it also plays a valuable role in the treatment of MAC and cryptosporidial infections.

Microsupplements

The benefit of micronutrient supplementation in PHA's is an increasingly accepted fact. Micronutrient depletion is a well documented finding in PHA's and is felt to contribute to overall morbidity. Although precise micronutrient dosing regimes have yet to be established, most physicians agree that 1-2 multivitamins per day, with additional anti-oxidant supplementation (Vitamin C, Vitamin E, betacaroten) is part of standard HIV care.

Category #2: Co-listing of N.F.B Products

The following list is of drugs presently covered under Non-Formulary Benefits. We understand that these drugs have the potential for overuse and misuse in self-limited medical conditions. The drugs below however, are so commonly used in HIV and their use is so widely accepted, that we propose they be co-listed on the Facilitated Access List. This would not only free physicians from the burden of additional paperwork, it would also decrease administrative costs in pharmacies and the Government:

Duragesic Patches
Oral Fucidin

Imodium
Intron A
Lactaid
Lomotil
Losec
Mycobutin
Ocular Lubricants
Roferon A
Tegretol
Trental
Liquid Nutritional Supplements

Category #3: Drugs to be Funded upon Licensure

Presently, many PHA's are living longer, better lives on medications obtained from the EDRP. Frequently a drug has become 'standard of care' before it is approved by HPB. Given the rapidly evolving nature of AIDS care this will no doubt continue. For this reason, a proactive approach to ODB-inclusion is essential. We illustrated above the paradox of access that occurred with Paromycin. While a drug is on EDRP we have open access. If that drug is found to be effective and is consequently approved by HPB, then our access is suddenly diminished. There must be coordination between the Government and front-line physicians to avoid this problem.

The list below is not meant to be exhaustive, but to illustrate a few drugs that will be licensed in the next year and are essential to PHA's.

Clofazimine

Clofazimine is a MAC treatment drug, provided free from the EDRP. We rely on it as part of MAC treatment protocols. Given the extreme difficulty in treating MAC and its severe morbidity, access to Clofazimine is essential.

Azithromycin 300mg Tablets

This is the dosage of Azithromycin used specifically in the AIDS-related opportunistic infections; toxoplasmosis, MAC and cryptosporidium. On licensure, this dosage allows easier compliance with the emerging treatment protocols.

Oral Gancyclovir/Gancyclovir Eye Implants

Any talk of CMV treatments carries fears of enormous governmental expenditures. Consideration of all such treatments must be in light of current costs. A consensus is emerging that the most effective and least toxic treatment is Oral Gancyclovir with the addition of eye implants if progression occurs. The cost of these treatments must be assessed based on the cost of Intravenous Gancyclovir therapy as well as the cost of treating the side effects iv therapy causes.

Category #4: Drugs in Need of Community and Government Discussion

This epidemic has prompted the development and use of drugs that represent a potentially enormous cost to Government. We recognize that no provincial government can provide blanket coverage of drugs like G-CSF, GM-CSF, EPO and rHGH. There are scenarios however, where their use may be economically acceptable. We request that this Government begin a dialogue with primary-care physicians, specialists and PHA's to define the roles these agents will play.