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COMPREHENSIVE DRUG DISTRIBUTION AND PAYMENT POLICY FOR DRUGS USED IN TREATMENT OF HIV AND HIV-RELATED ILLNESSES

BACKGROUND

HIV/AIDS is a catastrophic illness with no known cure, however individuals with HIV/AIDS can live productive lives with the assistance of drug therapies. Many of the drug therapies required to treat HIV and HIV-related illnesses are expensive. The majority (approximately 88%) of individuals with AIDS are between 20 and 49 years of age, an age at which individuals are establishing savings and equity. Some individuals with HIV/AIDS have third party insurance which covers their drug costs, some are eligible for the Ontario Drug Benefits (ODB) Program, and others do not have any drug coverage nor are they eligible for the ODB Program. Third party insurers often have limitations on total lifetime benefits, or the length of time an individual remains eligible for drug coverage while receiving long term disability benefits.

The Ministry of Health is spending \$9.0 million this fiscal year (91/92) on specific HIV-related drugs (zidovudine, aerosolized pentamidine, ddI) distributed through the HIV Project Centre at Sunnybrook Health Science Centre. An unknown amount is also spent through the Ontario Drug Benefit Program.

The drug therapies used to treat HIV and HIV-related illnesses can be hazardous if used inappropriately.

In the natural history of HIV disease, the initiation of zidovudine therapy is an indicator of an individual's need for additional and more expensive drugs as the individual is likely showing disease progression as well as having a low T4 cell count. Therefore, individuals who are eligible for zidovudine would be those most likely to become enrolled in the proposed program.

The AIDS Bureau of the Ministry of Health has established a working group to develop a policy to address eligibility, coverage, payment and distribution of drugs used to treat HIV and HIV-related illnesses. Participation in this working group includes: a primary care physician, an HIV/AIDS outpatient clinic director, a consumer, and members of the Drug Programs Branch and the AIDS Bureau of the ministry.

PURPOSE

The initial stimulus for developing the program as outlined below came from the need to address the financial hardship due to drug costs on those individuals who are not eligible for Ontario Drug Benefits and do not have third party insurance. The goal of this program is to facilitate access to drugs used to treat HIV and HIV-related illnesses.

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PRINCIPLES

The working group recommends that ministry policy on HIV/AIDS-related drugs be guided by the following principles:

1. Eligibility for the program will be based on a diagnosis of HIV infection or AIDS. Equitable coverage regardless of age, sexual orientation, income, geographical location, gender will be assured.
2. The policy for drugs used to treat HIV and HIV-related illnesses will be consistent with an overall ministry policy on coverage for drugs used to treat catastrophic illnesses.
3. A list of drug benefits for the treatment of HIV-related illnesses will be selected by an expert committee from among those drugs approved by the Health Protection Branch, Health and Welfare Canada and those non-approved drugs available through the Emergency Drug Release Program (Health and Welfare Canada). Not all drugs used in the treatment of HIV or HIV-related illnesses which are available in Canada will necessarily be covered under this policy.
4. For each drug on the benefits list, appropriate quality assurance mechanisms (clinical criteria, monitoring procedures, outcomes, evaluation) will be established as required.
5. All individuals who wish to receive benefits under the policy will be identified on a patient registry. Confidentiality of patient information included in and obtained through the patient registry is of paramount importance and will be strictly maintained.
6. Individuals who have third party coverage who wish to participate in the program will subrogate their coverage to the government for HIV-related drugs. Coverage for drugs used to treat other conditions (eg. heart disease) will not be subrogated for this program.
7. A budget specifically for drugs used to treat HIV and HIV-related illnesses be established within the Ministry of Health. A variety of sources may contribute to this budget.

MECHANISMS

List of Drug Benefits: A panel of experts, including physicians with specific expertise in treating individuals with HIV/AIDS (a specialist and a general practitioner), a pharmacist, a representative of consumers and a representative of each ministry program area, will be responsible for developing the list of drug benefits for treatment of HIV-related illnesses. The expert panel will also develop clinical guidelines for the prescribing of each of the drugs listed, along with monitoring guidelines. Mechanisms for distribution (community or hospital

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pharmacy) will be specified for each of the drugs on the list as appropriate to the prescribing and monitoring guidelines.

Access to the Program: Individual access will be through the HIV Project Centre at Sunnybrook Health Science Centre. Physicians will register individuals with HIV/AIDS on their caseloads with the HIV Project Centre. Until such time as the ministry has been linked to all the pharmacies in the province through an interactive computer system that would enable the pharmacist to instantaneously verify every individual's eligibility for particular lists of drugs, it may be possible to issue every individual in the HIV patient registry a drug card which would be honoured in complete confidentiality at local pharmacies designated across the province. Alternatively, if access to HIV/AIDS drugs is through designated local pharmacies, the HIV Project Centre could advise the designated pharmacies as chosen by the patients eligible to receive the drugs, in the same fashion as it now advises hospital pharmacies of those eligible to receive AZT and ddI. Patient consent forms will be required.

Drug Availability: Many drugs will be available through local community pharmacies. Some drugs with particular prescribing or monitoring requirements will continue to be distributed through the HIV Project Centre, Sunnybrook Health Science Centre to local hospital pharmacies. Emergency prescribing situations may be approved by telephone by the HIV Project Centre with the enrollment forms following.

HIV Project Centre, Sunnybrook Health Science Centre: The HIV Project Centre, Sunnybrook Health Science Centre will administer the entire program including: registering of individuals; determining the list of specific drugs to be covered in conjunction with the expert committee; ensuring that in all registered individual's cases, drugs are being prescribed using the guidelines developed by the expert committee; and monitoring and evaluating the program. The HIV Project Centre will send a list of participating eligible individuals to local designated community and hospital pharmacies.

Physician Buddy System: A physician buddy system will be established for physicians registered at the HIV Project Centre to ensure that physicians have access to up-to-date prescribing and treatment information, a second level of accountability for drug prescribing is established and that physicians inexperienced in treating HIV/AIDS are recruited and have access to a mentor who will be compensated by the ministry either at a flat rate (eg. \$250.00) for each inexperienced physician they coach or on a retainer basis. Mechanisms for evaluation and ensuring uniform standards of care will be built in at the start of the program. A pilot project of a physician buddy system for Metropolitan Toronto to be operated through the HIV Project Centre is currently being proposed. The project design and evaluation will be invaluable in the development of the system for the drug program.

Ontario Government Pharmaceutical and Medical Supply Services (OGPMSS): In order to

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maximize cost efficiency, the OGPMS (Ministry of Health) would be responsible for ordering the drugs in bulk and distributing to local community and hospital pharmacies.

Community and Hospital Pharmacies: Community and hospital pharmacies will order drugs from OGPMS for individuals who are registered with the HIV Project Centre. Payment of participating pharmacies for dispensing the drugs at a rate and basis will be determined.

RESPONSIBILITIES FOR PAYMENTS

One of the principles in the design of this policy is that of a variety of sources of funding. There are currently three areas that are paying for drugs used to treat HIV and HIV-related illnesses.

Third Party Insurers: All individuals who have third party drug coverage, who are registered at the HIV Project Centre, shall be entitled to coverage for their HIV-related drug needs by their third party insurer, to the limits provided in their individual plans. To ensure this and to facilitate administration, individuals with third party insurance will be asked to subrogate their drug benefits for designated HIV drugs to the Ontario Ministry of Health.

Ontario Drug Benefit Program: For individuals who are eligible for social assistance or are over 65 who are registered at the HIV Project Centre, the Ontario Drug Benefit Program will be responsible for payment of drugs covered under the HIV program.

Institutions Branch: Institutions Branch will be responsible for overall costs of administering the program incurred by the HIV Project Centre. In addition, Institutions Branch will be financially responsible for those individuals whose third party insurance has been exhausted, or are not eligible for an Ontario Drug Benefit card through social assistance or age. Ontario Drug Benefit's computerized claims processing system will be employed to process pharmacy claims for these groups, for drugs to be obtained through community and hospital pharmacies.

IMPLICATIONS

I INDIVIDUALS

Individuals with HIV/AIDS will be eligible to enter the program at any point in their disease. At the point of entry, individuals will be asked to designate a pharmacy or pharmacies for ordering their drugs. The HIV Project Centre will maintain a registry of individuals which will be sent to appropriate local community and hospital pharmacies (pharmacies will only receive the names of those individuals who will be using their services).

Individuals with third party insurance: For these individuals, a system of confidential

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submission of claims should be agreed upon by third party insurers and employers. Individual claims should no longer be processed in any manner which causes the transmission of confidential information through employer records. Access to the government-funded program would commence when third party coverage is exhausted. Individuals with third party insurance who wish to participate in this program will be required to subrogate their coverage to the Ministry of Health.

Individuals eligible for social assistance: Individuals with HIV/AIDS who receive social assistance would be automatically eligible for the drug coverage benefits included under this program.

Individuals without third party insurance and not eligible for social assistance: These individuals would be eligible to receive coverage of their drugs based on their clinical needs, not their financial needs. The implications would include being able to continue working without incurring debts due to drug costs and a reduction in social assistance costs.

II PRESCRIBING PHYSICIANS

Prescribing physicians would have clinical guidelines for the use of drugs, monitoring and availability of consultation through the HIV Project Centre thus ensuring a uniform standard of prescribing of drugs used to treat HIV and HIV-related illnesses. Currently only those physicians who are prescribing (or intending to prescribe) zidovudine, ddI and aerosolized pentamidine are technically eligible to obtain drug consultation services through the HIV Project Centre. Physicians who are treating individuals with HIV/AIDS who are not prescribing these drugs may not have access to reliable up-to-date information about drug therapies and the role of primary care physicians in treating HIV/AIDS. Using this model, it will be possible to establish a primary care physician buddy system by which primary care physicians with their first case of HIV or with few cases of HIV will be able to access primary care physicians with experience in treating individuals with HIV/AIDS in their practices.

Physicians acting as mentors to new physicians will receive a fee or stipend (to be determined) per inexperienced physician coached, or a retainer.

III FINANCIAL IMPLICATIONS

Third Party Insurers: Currently, third party insurers are only covering a portion of the drugs used in treating HIV-related illnesses. Specifically, third party insurers are not paying for AZT, ddI or aerosolized pentamidine. Insurers would be expected to pay for all drugs included in the program's list of benefits, up to the limits specified in the individual's coverage plan. Individuals would be required to subrogate their drug benefits to the Ministry of Health who would be responsible for ensuring prompt payment to the dispensers and recovery from third

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party insurers.

Ontario Drug Benefit Program: Currently, the Ontario Drug Benefit Program is covering all drugs approved as benefits under ODB for individuals with HIV/AIDS who are eligible for social assistance, over 65 or those who are registered in the home care program. There are no effective quality assurance mechanisms available under the Drug Benefit Program.

Institutions Branch: Institutions Branch is currently funding distribution and payment of zidovudine, ddI and aerosolized pentamidine through the HIV Project Centre at Sunnybrook Health Science Centre. It is being suggested that the current level of funding to the HIV Project Centre be maintained. Funding transferred from the ministry to the HIV Project Centre for the specific drugs would be obtained through the Ontario Drug Benefits Program and third party insurers. A mechanism for obtaining the additional funding will have to be developed.

IV MINISTRY OF HEALTH

The Ministry of Health will benefit from a system of distribution and payment of drugs used in the treatment of HIV and HIV-related illnesses through the development of a cost effective program that operates in partnership between the private and the public sector. The program can be easily monitored and evaluated and will be easily accessible to individuals in need.