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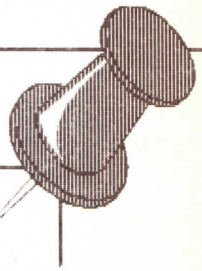

SUBJECT:

ATTN: GLEN BROWN/OCUFA/COMMUNICATIONS OFFICER
FROM: DR J GOODHEW
TEL: 461-2200

PLEASE CONTACT THIS OFFICE IF THIS TRANSMISSION IS INCOMPLETE. THANK YOU.

To: GLEN BROWN	From : Dr. William Barrie
For Information Call: 416-461-2200	At: DR. W. BARRIE AND DR. J. GOODHEW
Pages: 6	My Fax Number : 416-461-1210

Ontario

Ministry of Health / Ministère de la Santé

DRUG PROGRAMS BRANCH

Facsimile Transmission Form

TO:	Dr. J. Goodhew
DIVISION:	
ADDRESS:	
PHONE:	FAX: 461-1210

COMMENTS:

in conversation attached is a list of drugs - Aids Facilitated Access list & Note to Prescriber (to apply for unlisted drug products.

Thank you.

FROM: EXPEDITEUR:	J. Faubert
NAME:	MINISTRY OF HEALTH
BRANCH:	DRUG PROGRAMS BRANCH
ADDRESS:	3RD FLOOR, 5700 YONGE STREET, NORTH YORK, ONTARIO, M2M 4K5
PHONE:	(416) 327-8109 FAX NUMBER: (416) 327-8123

No. of Pages incl. Cover: 5 Time Sent: 12:40pm Date Sent: Feb 1/95

Ontario

Ministry of Health / Ministère de la Santé

Drug Programs Branch
3rd Floor, 5700 Yonge St.
North York, Ontario
M2M 4K5

Telephone: (416) 327-8109
Fax: (416) 327-8123

July, 1994

TO: All pharmacies

Re: Access to AIDS drugs for ODB eligible persons

The following is an update of new physicians that have been approved to participate in facilitated access, under ODB, to specific AIDS treatment drugs, **effective July 15, 1994.** These physicians are exempt from the usual paperwork associated with the provision of the products listed below (i.e., exempt from completion of the Non-Formulary Benefits Form, or from obtaining special approval and a drug supply number under Section 8), provided that the physician's College of Physicians and Surgeons of Ontario registration number also appears on the prescription for purpose of verification. College registration numbers have been provided with the list of physicians for your convenience. Coverage under facilitate access is limited to persons with a valid Ontario Drug Benefit eligibility card.

The following drugs have been included for facilitated access:

fluconazole	(Diflucan)
ganciclovir	(Cytovene)
acyclovir	(Zovirax)
pneumococcal vaccine	(Pneumovax)
nutrition products	**(only those products on the current list of approved NPs for patients who meet the functional impairment criteria)**
pyrimethamine	(Daraprim)
doxycycline	(various)

Please note that the participating prescriber's college registration number must be entered in the Prescriber Number field on regular claims and special claims forms, in order that the claims can be processed and pharmacies reimbursed under this special approval process.

PHARMACISTS ARE REMINDED THAT THE PHYSICIANS LIST AND INFORMATION CONTAINED IN THIS COMMUNICATION IS CONFIDENTIAL AND SHOULD NOT BE SHARED WITH NON-PHARMACY STAFF.

A list of new physicians that have been added to the ministry's list and authorized to receive Facilitated Access can be found on the back of this notice:

.../2

NOTE TO PRESCRIBERS

ONTARIO DRUG BENEFIT PROGRAM
COVERAGE OF UNLISTED DRUG PRODUCTS
(Requests under Section 8(1) of the Ontario Drug Benefit Act)

This Note to Prescribers outlines the Ontario Drug Benefit (ODB) program, and describes a mechanism available to make requests for coverage of drug products that are not listed as benefits under the ODB program (i.e. section 8). This Note also outlines the criteria used in reviewing such requests, what types of requests do not qualify for coverage under section 8 and what information prescribers are required to submit.

THE ODB PROGRAM

The ODB program is limited, both in terms of those eligible to receive benefits (i.e. persons 65 years of age and over, recipients of social assistance, persons eligible for home care and residents of long-term care facilities), and products covered (those identified under the provisions of the regulations). For persons eligible for the ODB program, **except those presenting with the most unusual or extraordinary conditions**, a complete range of prescription drug products is identified in the ODB Formulary and the list of Non-Formulary Benefits.

Products may be absent from these two lists for one or more of the following reasons:

- insufficient evidence of safety, efficacy or benefit relative to cost, in the population covered by the program;
- availability of appropriate alternatives (e.g., conventional dosage forms versus extended release listings or single drug entities rather than combination products);
- the manufacturer has not requested a listing for the drug product under the Ontario Drug Benefit Act, or such a request is currently being considered.

SECTION 8 REQUESTS

Under Section 8(1) of the Ontario Drug Benefit Act the Minister considers requests for coverage of drug products not listed in the Ontario Drug Benefit Formulary/Comparative Drug Index (ODBF/CDI) for ODB eligible persons. The ministry is guided by recommendations of the Drug Quality and Therapeutics Committee (DQTC) or other expert advisors when reviewing individual requests for coverage of drug products under Section 8.

The section 8 mechanism is reserved for requests for which there are NO FORMULARY ALTERNATIVES, to treat severe, life threatening or organ threatening conditions, or diseases that would otherwise cause severe debilitating effects; e.g. when an ODB-eligible person with a common condition cannot tolerate alternatives listed in the ODB Formulary because of unique clinical circumstances, or when an ODB-eligible person has a rare disease/condition and there is no suitable product listed in the Formulary, and the drug is not covered under another government program. **It is NOT intended to be used to request drugs to treat self-limiting conditions/symptoms, or for patient "convenience", or to continue patients previously enrolled in clinical trials of new drugs once these drugs are approved for marketing.**

In order to ensure a timely response to patients and their physicians and an approval process based on therapeutic benefits, fairness and consistency, the criteria for consideration of requests under the section 8 mechanism are outlined in this Note to Prescribers.

YOU ARE URGED TO REVIEW THIS NOTE TO PRESCRIBERS FULLY AND CAREFULLY, BEFORE SUBMITTING REQUESTS FOR COVERAGE OF UNLISTED DRUG PRODUCTS.

EXCLUDED PRODUCTS

The following DO NOT QUALIFY for coverage under section 8(1) of the Ontario Drug Benefit Act:

- Non-drug items, such as, but not limited to: devices; surgical supplies; chemicals; foods or nutrition products;

- Drug products which are not listed benefits in the ODB Formulary, but for which there are listed interchangeable products containing the same amount of the same active ingredient in the same dosage form. For example, products appearing in the Formulary with the phrase "Not a Benefit" (e.g. Valium, Percodan, Moduret) have designated interchangeable products listed and will therefore not be considered for coverage under section 8.

  Section 8 is not the appropriate mechanism for seeking coverage where the drug or drug product is made available to individuals through a ministry funding mechanism other than ODB, i.e. via another program, or where the drug is currently being evaluated for provision through a provincial program other than ODB (see box at right).

Examples of drugs provided through a ministry funding mechanism other than ODB:

. AZT (zidovudine)
. ddI (dideoxyinosine)
. ddC (zalcitabine)
. aerosol pentamidine
. erythropoietin (EPO)
. cyclosporine for solid organ transplants
. human growth hormone
. clozapine
. drugs used to treat cystic fibrosis thalassemia and end-stage renal disease

Examples of drugs provided through public health units:

. drugs for sexually transmitted diseases and pulmonary tuberculosis
. vaccines

As the Minister relies on the advice of the DQTC when considering coverage of an unlisted drug product in an individual's case, requests for the following will not generally be given favourable consideration:

- Products which have been specifically removed from the Formulary on the recommendation of the DQTC based on clinical, therapeutic and/or cost-effectiveness factors (e.g. certain non-prescription products like sunscreens, quinine sulfate and antihistamines).

- Products not licensed for sale in Canada.

- Products which the DQTC has reviewed and recommended not be paid for by the taxpayers of Ontario through the ODB program. These are generally products for which there are safer, more effective, or less costly products listed or alternatives available, or for which there is insufficient evidence of significant benefit relative to the cost of the product (see box at right).

- Extemporaneous preparations that are not designated pharmaceutical products.

Examples of products which the DQTC has evaluated and recommended not be paid under the ODB program:

. anorexiants (Tenuate, Ponderal)
. Ativan sublingual
. Bellergal spacetabs
. Climacteron
. Dixarit (clonidine is listed)
. Darvon N compound
. Efamol (Evening Primrose Oil)
. Fiorinal products and other analgesics containing barbiturates
. Psychotropic combination products (Etrafon D, Triavil)
. Nicotine replacement gum/patches
. Nitrong SR
. Serc
. Unit dose ocular lubricants
. Transdermal nitroglycerin patches
. 282 MEP
. Peripheral vasodilators (Hydergine, Cyclospasmol, Arlidin)
. Vitamin E
. Enteric-coated ferrous sulphate tablets
. unlisted OTC (non-prescription) products

- Products which have recently received federal approval for marketing in Canada, and are currently being formally reviewed by the DQTC for Formulary inclusion. This generally means products which have received federal approval in the last six months. Specific new drug products which offer significant therapeutic benefit to a number of individuals, or which represent a major therapeutic advance, will be made available early to eligible recipients through a "fast track" review.

APPLICATION MECHANISM

Drug Programs Branch co-ordinates the review of each request that includes a recommendation from the DQTC. The DQTC requires full details of an individual's case in order to make a recommendation. Your attention to the information requirements will ensure a complete and timely review by the DQTC. Requests that are not legible, that contain insufficient information, or that are requests for excluded products, will result in rejection of coverage and will be returned to the physician.

A physician must make a written request for individual ODB coverage of an unlisted drug product. Individuals must be eligible for coverage under the ODB program (i.e. persons 65 years of age and over, recipients of social assistance, persons eligible for home care and residents of long-term care facilities). Since each request is subject to a careful medical review, it is important that a full account be given of the clinical circumstances which appear to warrant coverage for the unlisted drug in a particular patient's case. Form letters are not individualized and are therefore not sufficient for the DQTC to review. The request must include a concise clinical description and therapeutic plan, and the patient's Health Number (HN) and ODB Eligibility Number, if different; and the physician's CPSO license number. Physicians must sign requests for coverage; stamps and proxy signatures will not be accepted.

Note: All patient and physician identifiers received or generated in the review process remain confidential. The ministry removes these identifiers prior to DQTC review.

Each section 8 request should be a concise clinical description and therapeutic plan which must include at a minimum:

- ✓ physician's name, address, telephone number, signature and CPSO license number;
- ✓ patient's name, sex and date of birth; Health Number (HN) of the individual and ODB Eligibility Number, if different;
- ✓ trade name, strength and dosage form of the requested drug product, and expected duration of therapy;
- ✓ specific diagnosis for which the drug is requested, or reason for use;
- ✓ if the patient has been taking the product, provide objective evidence of its efficacy;
- ✓ where alternative drug products are listed, or non-drug therapy may be appropriate, details of the alternatives tried including (for drugs) dosages, length of therapy and response to therapy;
- ✓ where alternatives are not appropriate, outline the reasons;
- ✓ concomitant drug therapy;
- ✓ other relevant information, e.g. culture and sensitivity reports, serum drug levels.

REIMBURSEMENT

The Ministry's decision on individual coverage in a particular patient's case will be communicated via letter to the physician making the request. If coverage is granted, a second copy of the letter will be provided to the physician, with instructions that the duplicate be forwarded to the pharmacy dispensing the drug. The letter is the authorization for a pharmacist to submit a claim to ODB for reimbursement for that drug product for that patient. Requests may be approved for a period of up to one year.

Coverage is NOT RETROACTIVE; that is, coverage is provided only after DQTC's recommendation and the ministry's decision in an individual case.

EXTENSION OF COVERAGE

If it is anticipated that a patient will continue to require the product beyond the last day of approval, the physician is required to request an extension of coverage at least 6 weeks prior to its expiration. Coverage will not be continued automatically between expiration and reissuance of approval. Requests for extension should include a summary of the patient's progress on the unlisted product, any changes in drug therapy, and the rationale for the continued need for the product.

Requests should be sent to the attention of:

Director
Drug Programs Branch
3rd Floor, 5700 Yonge Street
North York, Ontario M2M 4K5
Telephone: (416) 327-8109
Fax: (416) 327-8123