

Appendix O: Sample Request for an Unlisted Drug Product, IM Testosterone



Ontario

Ministry of Health
and Long-Term Care

Exceptional Access Program Branch
5700 Yonge Street 3rd floor
Toronto ON M2M 4K5

**Request for an Unlisted Drug Product
Exceptional Access Program (EAP)**

Please fax completed form and/or any additional relevant information to 416 327-7526 or toll-free 1 866 811-9908; or send to Exceptional Access Program Branch (EAPB), 3rd floor, 5700 Yonge Street, Toronto ON M2M 4K5. For copies of this and other EAP forms, please visit http://www.health.gov.on.ca/english/public/forms/form_menus/odb_fm.html

The Ministry of Health and Long-Term Care (the "ministry") considers requests for coverage of drug products not listed in the Ontario Drug Benefit Formulary under Section 16 of the Ontario Drug Benefit Act. This form is intended to facilitate requests for drugs under the Exceptional Access Program. The ministry may request additional documentation to support the request.

Please ensure that all appropriate information for each section is provided to avoid delays.

Section 1 – Prescriber Information

| | | |
|---|----------------------|-----------|
| First name sample | Initial | Last name |
| Mailing Address Street no. Street name | City | |
| | Postal code | |
| Fax no. () | Telephone no. () | |

Section 2 – Patient Information

| | | |
|----------------------------|---------|-----------|
| First name sample | Initial | Last name |
| Health Number | | |
| Date of birth (yyyy/mm/dd) | | |

New request Renewal of existing EAP approval (specify EAP#) _____

Section 3 – Drug Requested

| | |
|---|---|
| Requested drug product Depo-testosterone | DIN 00030783 |
| Strength / Dosage form 100 mg/mL, 1 mL IM, may require titration | Frequency of administration weekly, may require adjustment |
| Expected start date | Duration of therapy indefinite |

Section 4 – Diagnosis and Reason for Use

Diagnosis for which the drug is requested:
Gender Dysphoria

Reason for use over formulary alternatives:
No alternative on formulary

If the patient is currently taking the requested product, please provide start date & objective evidence of its efficacy:
Definitive improvement in psychosocial functioning and decrease in Gender Dysphoria

Section 5 – Current and / or Previous Medications

a) Please provide details of alternatives (listed drugs and/or non-drug therapy) tried for this condition:

| Name of drug (indicate if currently or previously taken) | Dosage | Approximate timeframe of therapy | Reason(s) why formulary alternatives are not appropriate |
|---|---|-------------------------------------|--|
| N/A | <input type="checkbox"/> current <input type="checkbox"/> previous | | |
| | <input type="checkbox"/> current <input type="checkbox"/> previous | | |
| | <input type="checkbox"/> current <input type="checkbox"/> previous | | |
| | <input type="checkbox"/> current <input type="checkbox"/> previous | | |

b) Provide patient's concomitant drug therapies for other conditions:

Section 6 – Clinical Information

Please provide relevant medical data (e.g. culture and sensitivity reports, serum drug levels, laboratory results):
Patient has been diagnosed with Gender Dysphoria and qualifies for hormone therapy

The information on this form is collected under the authority of the Personal Health Information Protection Act, 2004, S.O. 2004, c.3, Sched. A (PHIPA) and Section 13 of the Ontario Drug Benefit Act, R.S.O. 1990c.O.10 and will be used in accordance with PHIPA, as set out in the Ministry of Health and Long-Term Care "Statement of Information Practices", which may be accessed at www.health.gov.on.ca. If you have any questions about the collection or use of this information, call the Ontario Drug Benefit (ODB) Help Desk at 1 800 668-6641 or contact the Director, Exceptional Access Program Branch (EAPB), Ministry of Health and Long-Term Care, 3rd floor, 5700 Yonge St., Toronto ON M2M 4K5.

| | | |
|----------------------------------|-------------|------|
| Prescriber signature (mandatory) | CPSO number | Date |
|----------------------------------|-------------|------|