PART 3 EXCEPTION DRUG STATUS (EDS)

Certain drugs are approved for coverage under the Exception Drug Status (EDS) Program when they meet specific criteria and upon review and recommendation of the Manitoba Drug Standards and Therapeutics Committee (MDSTC). The drugs usually fall into one of the following categories:

- The drug is ordinarily administered only to hospital in-patients but is being administered outside of a hospital because of unusual circumstances.
- The drug is not ordinarily prescribed or administered in Manitoba, but is being prescribed because it is required in the diagnosis or treatment of an illness, disability, or condition rarely found in Manitoba.
- Evidence, including therapeutic and economic evidence, provided to the minister in accordance with the criteria established by him or her, supports a specific treatment regime which includes use of the drug or other item.

Over-the-counter (OTC) products are generally not included as benefits of the Drug Plan. Exception Drug Status is not granted for appetite suppressants, smoking cessation products, drugs for the treatment of erectile dysfunction and vaccines normally provided by Public Health.

When an EDS drug is approved as a benefit, the cost will be covered through the Pharmacare Program during the time period authorized by the EDS Program and after the clients Pharmacare deductible has been met.

INFORMATION REQUIRED WHEN MAKING A REQUEST FOR COVERAGE:

- Prescriber Information - Name (including first initial), Address, Phone Number and Prescriber Number.
- Client Information - Client Name, Address, Manitoba Health Registration Number (MHRN), Personal Health Identification Number (PHIN) and Date of Birth.
- Drug Information - Drug Name (trade and/or generic name), Dosage Form, Strength, Expected Dosing and Expected Therapy Duration.
- Justification - Diagnosis and/or Indications for Use.

NOTES REGARDING THE EXCEPTION DRUG STATUS (EDS) PROGRAM:

- Physicians, dentists, or other professionals authorized by physicians may apply for EDS.
- Requests can be submitted by telephone, by mail or by fax. A toll-free line with an electronic message system is available exclusively for requests on a 24-hour basis. The telephone number to access this line is (204) 788-6388 or 1-800-557-4303.
The fax number is (204) 942-2030 or 1-877-208-3588. <u>These numbers are for health professionals only</u>.
- To ensure eligible benefit coverage, approval must take place prior to purchase or dispensing of a prescription drug. Retroactive coverage is not provided.
- EDS requests are prioritized by date received and the urgency of the request.
- To ensure continuity of coverage, requests for renewal should be forwarded prior to the expiry date. Please allow at least two weeks for processing.
- Patients are notified by letter if a request for coverage has been approved or denied.
- If a drug is approved for coverage under EDS, coverage is valid from the date of application to date of expiration.
- If denied, payment for the medication is the responsibility of the patient.

NOTE: *Not all medications currently available on the market in Canada are benefits under the Manitoba Drug Benefits Formulary or under the EDS Program.*

PRODUCT SELECTION:

In September 2001, F/P/T Health Ministers agreed to establish a single Common Drug Review for new drugs (chemical entities) submitted in Canada for coverage by F/P/T drug plans. Beginning September 2003, all new drugs are reviewed nationally through the CDR process, with expert advice and recommendations being provided by the Canadian Agency for Drugs and Technologies in Canada. The recommendations of CADTH are taken into consideration by each jurisdiction when making a listing decision.
CADTH recommendations are taken into account by the Manitoba Drug Standards and Therapeutics Committee who makes recommendations to the Minister of Health on drug products to be considered for benefit under the Pharmacare Drug Benefit Program.
The MDSTC is independent of government and is comprised of physicians and pharmacists. Committee members provide recommendations on drug interchangeability and on the therapeutic and economic value of drug benefits.

For more information on the MDSTC, go to the following link:

http://www.gov.mb.ca/health/mdstc.html

For more information on the Manitoba Drug Benefits and Interchangeability Formulary, go to the following link:

http://www.gov.mb.ca/health/mdbif/

PROVINCIAL DRUG PROGRAMS REVIEW PROCESS (SPECIAL CIRCUMSTANCES):

Should a physician wish to obtain EDS status for a drug not normally eligible for Part 3 EDS status, the physician may apply in writing and include the information listed below.
Please address request to:

Provincial Drug Programs Review Committee
300 Carlton Street – Room 1014
Winnipeg MB R3B 3M9
Fax (204) 942-2030 or 1-877-208-3588.

Please include all of the information required for an EDS request (see page 1) as well as:

- Information and background on the original EDS request.
- Previous therapies tried and response to those therapies.
- Additional Information such as supporting literature to support the review.

CRITERIA:

Following are the criteria for coverage of ***common*** drugs requested under Exception Drug Status. Further information can be provided by professional staff at the Exception Drug Status program.

TABLE OF CONTENTS:

AUTONOMIC DRUGS

02232043 02232044	**Aricept**	donepezil	5 mg 10 mg	Tablets
02242115 02242116 02242117 02242118	**Exelon**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsules
02245240	**Exelon**	rivastigmine	2 mg/mL	Oral Liquid
02266717 02266725 02266733	**Reminyl ER**	galantamine	8 mg 16 mg 24 mg	Capsules

Confirmed diagnosis of Alzheimer's Disease with DSMIV criteria with:
(a) Memory impairment (impaired ability to learn new information or to recall previously learned information); plus
(b) at least one of the following:

- Aphasia; problems with language (receptive and expressive)
- Apraxia; impaired ability to carry out motor activities despite intact motor function
- Agnosia; failure of recognition - especially people
- Disturbance in executive functioning

The above deficits must have:

- Caused significant decline in previous levels; and
- A gradual onset and continued cognitive decline; and
- The absence of other causative conditions; and
- The deficits do not occur exclusively during the course of delirium; and
- Normal test results for all of the following values: CBC, TSH, Electrolytes, Vitamin B12, and Glucose; and
- The initial MMSE score must be between 10 and 26 and measured within 30 days of the application.

BLOOD FORMING AND COAGULATION

02132621 02132656 02132648 02132664 02231171	**Fragmin**	dalteparin	2500 IU/0.2 mL 2500 IU/mL 5000 IU/0.2 mL 10000 IU/mL 25000 IU/mL	Injection
02236913 02240114	**Fraxiparine**	nadroparin	9500 IU/mL 19000 IU/mL	Injection
02167859 02167840 02231478 02229515	**Innohep**	tinzaparin	3500 U/0.3 mL 10000 U/mL 10000 U/0.5 mL 200000 U/mL	Injection

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02012472 02236883 02242692 02236564	**Lovenox**	enoxaparin	30 mg/0.3 mL 100 mg/mL 120 mg/0.8 mL 300 mg/3 mL	Injection

Please contact the EDS Program at Manitoba Health for specific criteria.

CENTRAL NERVOUS SYSTEM AGENTS

Anorexigenic Agents and Respiratory and Cerebral Stimulants

02239665	**Alertec**	modafinil	100 mg	Tablets

1. To **treat narcolepsy** where:
(a) Amphetamines are contraindicated; OR
(b) Patients over 40 years old who have underlying cardiovascular disease or history of the disease; OR
(c) Patients have Parkinson's Disease or are unresponsive to methylphenidate (Ritalin) or dexamphetamine.
2. To treat patients with sleep lab confirmed diagnosis of narcolepsy, or idiopathic CNS hypersomnia.
3. To treat Multiple Sclerosis fatigue not responding to amantadine.

Anticonvulsants

02284294 02284308 02284316	**Apo-Oxcarbazepine**	oxcarbazepine	150 mg 300 mg 600 mg	Tablets
02242067 02242068 02242069	**Trileptal**	oxcarbazepine	150 mg 300 mg 600 mg	Tablets
02244673	**Trileptal**	oxcarbazepine	60 mg/mL	Liquid

For the treatment of patients with refractory partial epilepsy;
(a) when intolerant to other anticonvulsant therapy;
(b) adjunct therapy when current anticonvulsant therapies are not providing adequate seizure control.

Non-Steroidal Anti-Inflammatory Agents

02239941 02239942	**Celebrex**	celecoxib	100 mg 200 mg	Capsules
02248973 02248974	**Apo-Meloxicam**	meloxicam	7.5 mg 15 mg	Tablets
02250012 02250020	**Co Meloxicam**	meloxicam	7.5 mg 15 mg	Tablets
02255987 02255995	**Gen-Meloxicam**	meloxicam	7.5 mg 15 mg	Tablets
02242785 02242786	**Mobicox**	meloxicam	7.5 mg 15 mg	Tablets

02258315 02258325	**Novo-Meloxicam**	meloxicam	7.5 mg 15 mg	Tablets
02248267 02248268	**pms-Meloxicam**	meloxicam	7.5 mg 15 mg	Tablets
02247889 02248031	**ratio-Meloxicam**	meloxicam	7.5 mg 15 mg	Tablets

For the **long-term treatment of osteoarthritis or rheumatoid arthritis** in patients who have one or more of the following risk factors:

- Previous peptic ulcer, gastrointestinal bleeding, gastric outlet obstruction (endoscopy or radiographic evidence);
- Elderly (more than 65 years of age);
- Concurrent warfarin therapies;
- Bleeding disorders;
- Concurrent prednisone therapy at doses greater than 5 mg/day for more than 2 weeks; OR
- Where at least 3 NSAID's have been tried and failed or were not tolerated.

Also may approve for ankylosing spondilitis, gout, pseudo-gout, lupus or psoriatic arthritis.

NOTE: *If a patient is receiving a proton pump inhibitor (PPI) for reflux disease, COX II inhibitors are not warranted for additional protection.*

Opiate Agonists

02230302 02163748 02163780 02163799	**Codeine Contin**	codeine/oxycodone	50 mg 100 mg 150 mg 200 mg	Tablets

For the treatment of:

(a) **Palliative and chronic pain** in patients where hepatotoxicity is a concern due to high doses of acetaminophen (e.g. taking over 12 tablets of acetaminophen compound with codeine 30 mg per day).

(b) **Codeine addiction** using tapering doses.

02231934 02240131 02240132	**Oxy-IR**	oxycodone HCl	5 mg 10 mg 20 mg	Tablets
00789739 00443948 02262983	**Supeudol**	oxycodone HCl	5 mg 10 mg 20 mg	Tablets
00392480 00392472	**Supeudol**	oxycodone HCl	10 mg 20 mg	Suppositories

Patients who have tried the combination products (e.g. Percocet) and have maximized the acetaminophen dose or have contraindications to acetaminophen.

ELECTROLYTIC, CALORIC AND WATER BALANCE

02242814	**Apo-Lactulose**	lactulose	667 mg/mL	Oral Liquid
00703486	**pms-Lactulose**	lactulose	667 mg/mL	Oral Liquid
00854409	**ratio-Lactulose**	lactulose	667 mg/mL	Oral Liquid

Portal systemic encephalopathy.

EYE, EAR, NOSE AND THROAT PREPARATIONS

02248151	**Alphagan P**	brimonidine tartrate	0.15%	Ophthalmic Solution

Intolerance to Alphagan.

GASTROINTESTINAL DRUGS

02245058	**Apo-Omperazole**	omeprazole	20 mg	Capsules
02296446	**Sandoz Omperazole**	omeprazole	20 mg	Capsule

(a) For the **treatment of symptoms of gastroesophageal reflux disease** (GERD).
NOTE: Patients with non-erosive GERD could potentially be reduced to step-down therapy with an H2 antagonist depending on symptom resolution. Patients may also be trialed by dosing on alternate days or by using a lower dose PPI.
e.g. Pariet 10mg –one tablet per day instead of 2 tablets per day.
(b) For **gastro-protection for NSAID's**: (The PPI may be approved for as long as the patient continues on a traditional NSAID – Coverage is renewable on a yearly basis for patients if discontinuation of offending agents or replacement with less damaging alternatives is not feasible). For use in the prevention of NSAID induced ulcers in patients who continue on a non-selective NSAID therapy and who have any one of the following risk factors:

- History of peptic or duodenal ulcer
- Age >65 years
- Concomitant warfarin use
- Concomitant corticosteroid use

(c) For **Peptic Ulcer Treatment** (The PPI may be approved for 8 weeks of therapy).
(d) For PPIs in **Zollinger-Ellison Syndrome and Barrett's Esophagus**.
(The PPI may be approved for a 3-year treatment course).

02190915	**Losec**	omeprazole	20 mg	Tablets
00846503	**Losec**	omeprazole	20 mg	Capsules
02229453	**Pantoloc***	pantoprazole	40 mg	Enteric Coated Tablets
02243796 02243797	**Pariet**	rabeprazole	10 mg 20 mg	Enteric Coated Tablets
02165503 02165511	**Prevacid***	lansoprazole	15 mg 30 mg	Sustained Release Capsules
02260867	**ratio-Omeprazole**	omeprazole	20 mg	Tablet

cont…

(a) For the **treatment of symptoms of gastroesophageal reflux disease** (GERD).
NOTE: *Patients with non-erosive GERD could potentially be reduced to step-down therapy with an H2 antagonist depending on symptom resolution. Patients may also be trialed by dosing on alternate days or by using a lower dose PPI.*
e.g. Pariet 10mg –one tablet per day instead of 2 tablets per day.
(b) For **gastro-protection for NSAID's**: (The PPI may be approved for as long as the patient continues on a traditional NSAID – Coverage is renewable on a yearly basis for patients if discontinuation of offending agents or replacement with less damaging alternatives is not feasible). For use in the prevention of NSAID induced ulcers in patients who continue on a non-selective NSAID therapy and who have any one of the following risk factors:

- History of peptic or duodenal ulcer
- Age >65 years
- Concomitant warfarin use
- Concomitant corticosteroid use

(c) For **Peptic Ulcer Treatment** (The PPI may be approved for 8 weeks of therapy).
(d) For **H. pylori Eradication** (The PPI may be approved for a 7-14 day treatment course).
(e) For PPIs in **Zollinger-Ellison Syndrome and Barrett's Esophagus**.
(The PPI may be approved for a 3-year treatment course).

***NOTE:** *Omeprazole and rabeprazole must have been tried and failed or not tolerated.*

02244522	**Nexium**	esomprazole	40 mg	Tablet

Nexium will be approved for the following criteria when the patient is currently prescribed or the prescriber is considering prescribing a PPI including for patients who are being considered for PPI therapy above the recommended daily dose (for example, doses greater than once daily) of any other PPI:
(a) For the treatment of symptoms of gastroesophageal reflux disease (GERD) (approved for 3 years)
NOTE: Patients with non-erosive GERD could potentially be reduced to step-down therapy with an H2 antagonist depending on symptom resolution. Patients may also be trialed by dosing on alternate days or by using a lower dose PPI.
e.g. Pariet 10mg –one tablet per day instead of 2 tablets per day.
(b) For gastro-protection for NSAID's: (approved for as long as the patient continues on a traditional NSAID patients who continue on a non-selective NSAID therapy and who have any one of the following risk factors:
– Coverage is renewable on a yearly basis for patients if discontinuation of offending agents or replacement with less damaging alternatives is not feasible). For use in the prevention of NSAID induced ulcers in:

- History of peptic or duodenal ulcer
- Age >65 years
- Concomitant warfarin use
- Concomitant corticosteroid use

(c) For Peptic Ulcer Treatment (approved for 8 weeks of therapy).
(d) For H. pylori Eradication (approved for a 7-14 day treatment course).
(e) For use for Zollinger-Ellison Syndrome (approved for up to a 3-year treatment course).

02212005	**Apo-Loperamide**	loperamide	2 mg	Tablets
02229552	**Diarr-eze**	loperamide	2 mg	Tablets
02183862	**Imodium**	loperamide	2 mg	Tablets
02132591	**Novo-Loperamide**	loperamide	2 mg	Tablets
02228351	**pms-Loperamide**	loperamide	2 mg	Tablets
02233998	**Rhoxal-loperamide**	loperamide	2 mg	Tablets
02257564	**Sandoz Loperamide**	loperamide	2 mg	Tablets

For the treatment of:
(a) Ileostomy or a colostomy;
(b) Bowel resection, including short bowel syndrome;
(c) Inflammatory bowel diseases, e.g. Crohn's Disease, Ulcerative Colitis;
(d) Cancer including chemotherapy and radiation therapy;
(e) HIV/AIDS;
(f) Fecal incontinence.

HORMONES AND SYNTHETIC SUBSTITUTES

02229293	**Entocort**	budesonide	3 mg	Capsules

Crohn's Disease of ileum or ascending colon (right-sided disease).

02247585	**Apo-Calcitonin**	calcitonin	200 IU/mL	Nasal Spray
02240775	**Miacalcin**	calcitonin	200 IU/mL	Nasal Spray
02261766	**Sandoz Calcitonin**	calcitonin	200 IU/mL	Nasal Spray

(a) Short term management of pain associated with acute spinal fracture (maximum coverage 12 weeks).
(b) For the treatment of osteoporosis in patients who are intolerant or have contraindications to bisphosphonates.

02242572 02242573 02242574	**Actos**	pioglitazone	15 mg 30 mg 45 mg	Tablets
02302942 02302950 02302977	**Apo-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablets
02302861 02302888 02302896	**Co Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet
02298279 02298287 02298295	**Gen-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablets
02274914 02274922 02274930	**Novo-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablets
02303124 02303132 02303140	**pms-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet

02301423 02301431 02301458	**ratio-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet
02297906 02297914 02297922	**Sandoz Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet

For use in patients who are not optimally controlled on maximal doses of metformin and either a sulfonylurea (glyburide, gliclazide) or repaglinide or with contraindications to these agents.
Type 2 diabetics on high doses of insulin (over 2 U/kg) and on maximally tolerated metformin who are not achieving optimal control.

NOTE: *Actos should be used as an add-on to pre-existing therapy not a substitution.*

02245272 02245273 02245274	**Amaryl**	glimepiride	1 mg 2 mg 4 mg	Tablets
02274248 02274272 02274256	**Co Glimepiride**	glimepiride	1 mg 2 mg 4 mg	Tablets
02273756 02273764 02273772	**Novo-Glimepiride**	glimepiride	1 mg 2 mg 4 mg	Tablets
02273101 02273128 02273136	**ratio-Glimepiride**	glimepiride	1 mg 2 mg 4 mg	Tablets
02269589 02269597 02269619	**Sandoz Glimepiride**	glimepiride	1 mg 2 mg 4 mg	Tablets

For patients poorly controlled on maximum doses of glyburide or gliclazide and metformin and diet (unless metformin is contraindicated because of renal/hepatic dysfunction or G.I. intolerance.)

02239924 02239925 02239926	**Gluconorm**	repaglinide	0.5 mg 1 mg 2 mg	Tablets

(a) Inadequate control on maximum doses of glyburide and metformin.
(b) Frequent or severe hyglycemic events despite dosage adjustments of glyburide or gliclazide.

SMOOTH MUSCLE RELAXANTS

02239064 02239065	**Detrol**	tolteradine	1 mg 2 mg	Tablets
02244612 02244613	**Detrol LA**	tolteradine	2 mg 4 mg	Extended Release Tablets

02243960 02243961	**Ditropan XL**	oxybutynin	5 mg 10 mg	Extended Release Tablets
02254735	**Oxytrol**	oxybutynin	36 mg	Transdermal Patches
02275066	**Trosec**	trospium	20 mg	Tablets

Urinary incontinence in patients unable to tolerate or failing oxybutynin (Ditropan) e.g. headache, dry mouth, dyspepsia.

UNCLASSIFIED THERAPEUTIC AGENTS

02242518 02246896	**Actonel**	risedronate	5 mg 35 mg	Tablets
02239028	**Evista**	raloxifene	60 mg	Tablets
02248728 02248730	**Apo-Alendronate**	alendronate sodium	10 mg 70 mg	Tablets
02258110	**Co Alendronate**	alendronate sodium	70 mg	Tablets
02270129 02286335	**Gen-Alendronate**	alendronate sodium	10 mg 70 mg	Tablets
02201011 02245329	**Fosamax**	alendronate sodium	10 mg 70 mg	Tablets
02247373 02261715	**Novo-Alendronate**	alendronate sodium	10 mg 70 mg	Tablets
02273179	**pms-Alendronate**	alendronate sodium	70 mg	Tablets
02284006	**pms-Alendronate FC**	alendronate sodium	70 mg	Tablets
02275279	**ratio-Alendronate**	alendronate sodium	70 mg	Tablets
02288087 02288109	**Sandoz Alendronate**	alendronate sodium	10 mg 70 mg	Tablets

For the treatment of patients with:
(a) Osteoporotic fractures;
(b) Osteoporosis diagnosed with bone mineral density (BMD) measurements by any approved technology, e.g. a T score of < - 2.5; or
(c) x-ray diagnosis of osteoporosis.

NOTE: *Concurrent calcium and vitamin D supplementation is recommended.*

02258102	**Co Alendronate**	alendronate sodium	40 mg	Tablets
02201038	**Fosamax**	alendronate sodium	40 mg	Tablets

For the treatment of **Paget's Disease.**

02280191 02280205	**Novo-Betahistine**	betahistine	16 mg 24 mg	Tablets
02243878 02247998	**Serc**	betahistine	16 mg 24 mg	Tablets

For the treatment of **Meniere's Disease.**

02244324	**Apo-Cyclosporine**	cyclosporine	100 mg/mL	Solution

02150689 02160662 02150670	**Neoral**	cyclosporine	25 mg 50 mg 100 mg	Capsules
02150697	**Neoral**	cyclosporine	100 mg/mL	Solution
02247073 02247074 02242821	**Rhoxal-cyclosporine**	cyclosporine	25 mg 50 mg 100 mg	Capsules

(a) Psoriases resistant to topical treatments (steroids, coal tar), systemic retinoids, MTX, hydroxyurea, PUVA, UVB treatment.
(b) Rheumatoid arthritis.
(c) Pediatric nephrotic syndrome.
(d) Vasculitis failing other therapies such as steroids, Imuran.
(e) Aplastic anemia.
(f) Inflammatory bowel disease.
(g) Where prescribed by a neurologist for the treatment of myasthenia gravis refractory to azathioprine, with or without steroids or where azathioprine is contraindicated.

NOTE: *TRANSPLANT patients are covered under the WRHA Hospital Insured Program at HSC Psychiatry Pharmacy, phone number (204) 787-7440.*

02242903 02274728	**Enbrel**	etanercept	25 mg 50 mg/mL	Injection
02258595	**Humira**	adalimumab	40 mg/0.8 mL	Injection
02245913	**Kineret**	anakinra	150 mg/mL	Injection
02244016	**Remicade**	infliximab	100 mg/10 mL	Injection

Specialists in gastroenterology and rheumatology may apply for Part 3 EDS in writing. Please contact the EDS Program at MB Health for specific criteria.

02237770	**Avonex**	interferon beta 1-a	30 mcg	Injection
02269201	**Avonex**	interferon beta 1-a	30 mcg/0.5 mL	Injection
02277492	**Rebif**	interferon beta 1-a	8.8 mcg/0.5 mL	Injection
02237319	**Rebif**	interferon beta 1-a	22 mcg/0.5 mL	Injection
02237320	**Rebif**	interferon beta 1-a	44 mcg/0.5 mL	Injection
02281708	**Rebif Initiation Pack**	interferon beta 1-a	8.8 mcg 22 mcg	Injection
02237317	**Rebif with Diluent**	interferon beta 1-a	11 mcg	Injection
02237318	**Rebif with Diluent**	interferon beta 1-a	44 mcg	Injection
02169649	**Betaseron**	interferon beta 1-b	0.3 mg	Injection
02233014	**Copaxone**	glatiramer acetate	20 mg/2 mL	Injection
02245619	**Copaxone**	glatiramer acetate	20 mg/mL	Pre-Filled Syringe

Specialists from the MS Clinic may apply for Part 3 EDS. Please contact the EDS Program at MB Health for specific criteria.

02059762 02059789	**Aredia**	pamidronate disodium	3 mg/mL 9 mg/mL	Injection
02244550 02244552	**Pamidronate Disodium**	pamidronate disodium	3 mg/mL 9 mg/mL	Injection
02264951 02264986	**Rhoxal-pamidronate**	pamidronate disodium	3 mg/mL 9 mg/mL	Injection

Patients unable to absorb oral medications due to Crohn's Disease or other absorption problems (use for the treatment of osteoporosis).

02243144 02175991 02175983	**Prograf**	tacrolimus	0.5 mg 1 mg 5 mg	Capsules
02176009	**Prograf**	tacrolimus	5 mg/mL	Injection
00960632	**Prograf**	tacrolimus	0.5 mg/ mL	Suspension

(a) For the prophylaxis of organ rejection in patients receiving allogeneic liver or kidney transplants.
(b) For use in atopic dermatitis resistant to potent steroids and oral cyclosporine.

02192748 00960601	**Cellcept**	mycophenolate mofetil	250 mg 50 mg/mL	Capsules
02242145	**Cellcept**	mycophenolate mofetil	200 mg/mL	Injection
02237484	**Cellcept**	mycophenolate mofetil	500 mg	Tablets

(a) Transplant patients.
(b) Lupus nephritis refractory to I.V. cyclophosphamide.
(c) Glomerular disease resistant or relapsing steroid treatment and/or alkylating agents.
(d) Severe psoriasis failing PUVA, acitretin and immunosuppressants (e.g. MTX, Neoral).
Bullous pemphigoid or autoimmune hepatitis for patients who are intolerant of steroids and azathioprine.

02248540	**Apo-Tryptophan**	l-tryptophan	500 mg	Capsules
02248538 02248539	**Apo-Tryptophan**	l-tryptophan	500 mg 1 g	Tablets
02241023	**pms-Tryptophan**	l-tryptophan	500 mg	Capsules
02240445 02230202	**pms-Tryptophan**	l-tryptophan	500 mg 1 g	Tablets
02240334	**ratio-Tryptophan**	l-tryptophan	500 mg	Capsules
02240333 02237250	**ratio-Tryptophan**	l-tryptophan	500 mg 1 g	Tablets
00718149	**Tryptan**	l-tryptophan	500 mg	Capsules
02029456 00654531	**Tryptan**	l-tryptophan	500 mg 1 g	Tablets

Adjunct therapy for refractory depression. Must have tried at least 2 other antidepressants.

02256495 02256509	**Apo-Leflunomide**	leflunomide	10 mg 20 mg	Tablet

02241888 02241889	**Arava**	leflunomide	10 mg 20 mg	Tablet
02261251 02261278	**Novo-Leflunomide**	leflunomide	10 mg 20 mg	Tablet
02288265 02288273	**pms-Leflunomide**	leflunomide	10 mg 20 mg	Tablet
02283964 02283972	**Sandoz Leflunomide**	leflunomide	10 mg 20 mg	Tablet

Rheumatoid arthritis failing at least 2 disease modifying antirheumatic drugs (DMARDs), eg. gold, methotrexate (MTX), plaquenil, sulfasalazine, minocycline and doxycycline.