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, 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:

- Health professionals who have prescribing authority 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.

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.

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AUTONOMIC DRUGS

02336715 02336723 02336731 02336758	**Apo-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsules
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
02339439 02339447 02339455	**Mylan-Galantamine ER**	galantamine	8 mg 16 mg 24 mg	Capsules
02332809 02332817 02332825 02332833	**Mylan-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsules
02305984 02305992 02306018 02306026	**Novo-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsules
02316943 02316951 02316978	**PAT-Galantamine ER**	galantamine	8 mg 16 mg 24 mg	Capsules
02306034 02306042 02306050 02306069	**pms-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsules
02311283 02311291 02311305 02311313	**ratio-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsules
02266717 02266725 02266733	**Reminyl ER**	galantamine	8 mg 16 mg 24 mg	Capsules
02324563 02324571 02324598 02324601	**Sandoz Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsules

02377950 02377969 02377977	**Teva-Galantamine**	galantamine	8 mg 16 mg 24 mg	Tablets

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.

02246793	**Spiriva**	tiotropium	18 mcg	Capsules

For patients with moderate to severe COPD who remain symptomatic despite an adequate trial (3 months) of ipratropium.

BLOOD FORMING AND COAGULATION

02132621 02132656 02132648 02132664 02231171 02352680 02352648 02352672 02352656 02352664	**Fragmin**	dalteparin	2500 IU/0.2 mL 2500 IU/mL 5000 IU/0.2 mL 10000 IU/mL 25000 IU/mL 18000 IU/0.72 mL 7500 IU/0.3 mL 15000 IU/0.6 mL 10000 IU/0.4 mL 12500 IU/0.5 mL	Injection
02236913 02240114	**Fraxiparine**	nadroparin	9500 IU/mL 19000 IU/mL	Injection
02229755 02167840 02231478 02229515 02358182 02358158 02358166 02358174	**Innohep**	tinzaparin	2500 IU/0.25 mL 10000 IU/mL 10000 IU/0.5 mL 200000 IU/mL 18000 IU/0.9 mL 3500 IU/0.35 mL 4500 IU/0.45 mL 14000 IU/0.7 mL	Injection

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.

02316986	**Xarelto**	rivaroxaban	10 mg	Tablet

For the prophylaxis of venous thromboembolism following total knee replacement for up to two (2) weeks, and following total hip replacement surgery for up to five (5) weeks, as an alternative to low molecular weight heparins.

02312441 02358808	**Pradax**	dabigatran	110 mg 150 mg	Capsules
02378604 02378612	**Xarelto**	rivaroxaban	15 mg 20 mg	Tablets

At-risk patients with non-valvular atrial fibrillation who require dabigatran or rivaroxaban for the preventi of stroke and systemic embolism AND in whom:
(a) Anticoagulation is inadequate following a reasonable trial on warfarin; **OR**
(b) Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

02273233 02273284 02273241 02273292 02273268 02273306 02273276 02273314	**Caduet**	amlodipine/atorvastatin	5/10 mg 10/10 mg 5/20 mg 10/20 mg 5/40 mg 10/40 mg 5/80 mg 10/80 mg	Tablets

For patients who have been titrated to a stable combination, for a minimum of at least 3 months, of the separate components, amlodipine besylate and atorvastatin.

CENTRAL NERVOUS SYSTEM AGENTS

Anorexigenic Agents and Respiratory and Cerebral Stimulants

02239665	**Alertec**	modafinil	100 mg	Tablets
02285398	**Apo-Modafinil**	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.

02247027 02247028 02247029	**Keppra**	levetiracetam	250 mg 500 mg 750 mg	Tablets
02285924 02285932 02285940	**Apo-Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablets
02274183 02274191 02274205	**CO Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablets
02296101 02296128 02296136	**pms-Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablets

As an add-on anticonvulsant.

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	**Mylan-Meloxicam**	meloxicam	7.5 mg 15 mg	Tablets
02242785 02242786	**Mobicox**	meloxicam	7.5 mg 15 mg	Tablets
02258315 02258323	**Teva-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	50 mg 100 mg 150 mg 200 mg	Sustained Release 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
02319977 02319985 02319993	**pms-Oxycodone**	oxycondone 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.

02372525 02372533 02372797 02372541 02372568 02372576 02372584	**OxyNeo**	oxycodone	10 mg 15 mg 20 mg 30 mg 40 mg 60 mg 80 mg	Controlled Released Tablets

For the diagnosis of:
1. Cancer related pain; PLUS
Patients who are unable to tolerate or receive an adequate response to either the regular release dosage forms of oxycodone or the sustained release preparations of morphine or hydromorphone; OR
2. Pain management in a specified chronic pain diagnosis (details regarding patient's condition and previous medication history are required); PLUS
Patients who are unable to tolerate or receive an adequate response to either the regular release dosage forms of oxycodone or the sustained release preparations of morphine or hydromorphone.

Selective Serotonin and Norepinephrine Reuptake Inhibitors

02301482 02301490	**Cymbalta**	duloxetine	30 mg 60 mg	Capsule

For the treatment of:
1. **Diabetic peripheral neuropathic pain** in patients who are unresponsive to two adequate courses of less costly alternative agents such as a tricyclic antidepressant agent or an anticonvulsant agent. The dose of duloxetine should be limited to a maximum of 60 mg daily.
2. **Depression** after lack of response and/or intolerance to at least two other antidepressants.

ELECTROLYTIC, CALORIC AND WATER BALANCE

02242814	**Apo-Lactulose**	lactulose	667 mg/mL	Oral Liquid
02247383	**Euro-LAC**	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
02301334	**Apo-Brimonidine P**	brimonidine tartrate	0.15%	Ophthalmic Solution

Intolerance to brimonidine 0.2%.

GASTROINTESTINAL DRUGS

02339102	**Apo-Esomeprazole**	esomeprazole	40 mg	Tablets
02293811 02293838	**Apo-Lansoprazole**	lansoprazole	15 mg 30 mg	Tablets
02292912 02292920	**Apo-Pantoprazole***	pantoprazole	20 mg 40 mg	Tablets
02300486	**CO Pantoprazole***	pantoprazole	40 mg	Tablets
02299585	**Mylan-Pantoprazole***	pantoprazole	40 mg	Tablets
02353830 02353849	**Mylan-Lansoprazole**	lansoprazole	15 mg 30 mg	Capsules
02280515 02280523	**Novo-Lansoprazole DR***	lansoprazole	15 mg 30 mg	Sustained Release Capsules
02285479 02285487	**Novo-Pantoprazole***	pantoprazole	20 mg 40 mg	Tablets
02381737 02381745	**PAT-Rabeprazole**	rabeprazole	10 mg 20 mg	Tablets
02320851	**pms-Omeprazole**	omeprazole	20 mg	Capsules
02307863 02307871	**pms-Pantoprazole***	pantoprazole	20 mg 40 mg	Tablets
02298074 02298082	**Ran-Rabeprazole**	rabeprazole	10 mg 20 mg	Tablets
02308681 02308703	**ratio-Pantoprazole***	pantoprazole	20 mg 40 mg	Tablets
02296446	**Sandoz Omperazole**	omeprazole	20 mg	Capsules

02301075 02301083	**Sandoz Pantoprazole***	pantoprazole	20 mg 40 mg	Tablets
02314177 02314185	**Sandoz Rabeprazole**	rabeprazole	10 mg 20 mg	Tablets

(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).

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

02245058	**Apo-Omeprazole**	omeprazole	20 mg	Capsules
02345579 02345587	**Apo-Rabeprazole**	rabeprazole	10 mg 20 mg	Tablets
02190915	**Losec**	omeprazole	20 mg	Tablets
00846503	**Losec**	omeprazole	20 mg	Capsules
02329433	**Mylan-Omeprazole**	omeprazole	20 mg	Capsules
02244522	**Nexium**	esomeprazole	40 mg	Tablets
02229453	**Pantoloc***	pantoprazole	40 mg	Enteric Coated Tablets
02243796 02243797	**Pariet**	rabeprazole	10 mg 20 mg	Enteric Coated Tablets
02310260	**pms-Omeprazole DR**	omeprazole	20 mg	Tablets
02165503 02165511	**Prevacid***	lansoprazole	15 mg 30 mg	Sustained Release Capsules
02296632 02296640	**Teva-Rabeprazole EC**	rabeprazole	10 mg 20 mg	Tablets
02310805 02310813	**pms-Rabeprazole EC**	rabeprazole	10 mg 20 mg	Tablets

02305038 02305046	**Ran-Pantoprazole***	pantoprazole	20 mg 40 mg	Tablets
02260867	**ratio-Omeprazole**	omeprazole	20 mg	Tablets

(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.*

02238528	**HP-Pac**	amoxicillin/clarithromycin/ lansoprazole	500 mg 500 mg 30 mg	Tablets

For H. pylori Eradication (approved for a 7-14 day treatment course).

02212005	**Apo-Loperamide**	loperamide	2 mg	Tablets
02256452	**Jamp-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
02303442 02303450 02303469	**Accel-Pioglitazone**	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	Tablets
02298279 02298287 02298295	**Mylan-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablets
02274914 02274922 02274930	**Novo-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablets
02326477 02326485 02326493	**Mint-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablets
02303124 02303132 02303140	**pms-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablets

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

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: *Pioglitazone 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
02295377 02295385 02295393	**Apo-Glimepiride**	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.)

02355663 02355671 02355698	**Apo-Repaglinide**	repaglinide	0.5 mg 1 mg 2 mg	Tablets
02321475 02321483 02321491	**CO Repaglinide**	repaglinide	0.5 mg 1 mg 2 mg	Tablets
02239924 02239925 02239926	**Gluconorm**	repaglinide	0.5 mg 1 mg 2 mg	Tablets

02357453 02357461 02357488	**Sandoz Repaglinide**	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.

02245689 02251930 02294338	**Lantus**	insulin glargine	100 IU/mL	Injection

First line alternative, secondary to NPH and/or premix at daily optimal dose, for patients who have been diagnosed with Type 1 or Type 2 diabetes AND who have experienced unexplained nocturnal hypoglycemia at least once a month despite optimal management OR have documented severe or continuing systemic or local allergic reaction to existing insulin.

02303922	**Januvia**	sitagliptin	100 mg	Tablets

For the treatment of patients with type 2 diabetes who have previously been treated with metformin and a sulfonylurea. Januvia should be used in patients with diabetes who are not adequately controlled on or are intolerant to metformin and a sulfonylurea, and for whom insulin is not an option.

02375842 02333554	**Ongylza**	saxagliptin	2.5 mg 5 mg	Tablets

For the treatment of patients with type 2 diabetes who have previously been treated with metformin and a sulfonylurea. Onglyza should be used in patients with diabetes who are not adequately controlled on or are intolerant to metformin and a sulfonylurea, and for whom insulin is not an option.

SMOOTH MUSCLE RELAXANTS

02239064 02239065	**Detrol**	tolterodine	1 mg 2 mg	Tablets
02244612 02244613	**Detrol LA**	tolterodine	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
02277263 02277271	**Vesicare**	solifenacin	5 mg 10 mg	Tablets

Urinary incontinence in patients unable to tolerate or failing immediate release oxybutynin e.g. headache, dry mouth, dyspepsia.

UNCLASSIFIED THERAPEUTIC AGENTS

02242518 02246896	**Actonel**	risedronate	5 mg 35 mg	Tablets
02353687	**Apo-Risedronate**	risedronate	35 mg	Tablets
02298376 02298392	**Novo-Risedronate**	risedronate	5 mg 35 mg	Tablets
02239028	**Evista**	raloxifene	60 mg	Tablets
02279215	**Apo-Raloxifene**	raloxifene	60 mg	Tablets
02312298	**Novo-Raloxifene**	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	**Mylan-Alendronate**	alendronate sodium	10 mg 70 mg	Tablets
02357984	**Mylan-Risedronate**	risedronate	35 mg	Tablets
02201011 02245329	**Fosamax**	alendronate sodium	10 mg 70 mg	Tablets
02247373 02261715	**Teva-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.*

02239146	**Actonel**	risedronate	30 mg	Tablets
02298384	**Novo-Risedronate**	risedronate	30 mg	Tablets
02258102	**CO Alendronate**	alendronate sodium	40 mg	Tablets
02201038	**Fosamax**	alendronate sodium	40 mg	Tablets

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

02343541	**Prolia**	denosumab	60 mg/mL	Injection

1. Female patients with Post Menopausal Osteoporosis (PMO) at high risk for fracture and satisfy at least two of the following three criteria:
   - Age > 75 years;
   - A prior fragility fracture;
   - A bone mineral density (BMD) T-score ≤ -2.5; or
2. Female patients with PMO with a serious intolerance to oral bisphosphonates or for who oral bisphosphonates are contraindicated.

02368153	**Xgeva**	denosumab	120 mg	Injection

For the prevention of skeletal-related events (SREs) in patients with castrate-resistant prostate cancer with one or more documented bony metastases and good performance status (ECOG performance status score of 0, 1 or 2).

02374757 02374765	**CO Betahistine**	betahistine	16 mg 24 mg	Tablets
02280183 02280191 02280205	**Teva-Betahistine**	betahistine	8 mg 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) Psoriasis 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.*

02282097	**Orencia**	abatacept	250 mg/vial	Injection

For treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis and who have failed treatment with at least 3 DMARDs (disease-modifying antirheumatic drugs) therapies one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented.
One combination therapy of DMARDs must also be tried.

Request for coverage must be made by a physician who is a specialist in rheumatology.

02242903 02274728	**Enbrel**	etanercept	25 mg 50 mg/mL	Injection

Rheumatoid Arthritis:
For treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARD's must also be tried.
Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

Request for coverage must be by a specialist in rheumatology.

Psoriatic Arthritis:
For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented.
One combination therapy of DMARD's must also be tried.
Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

Request for coverage must be made by a specialist in rheumatology.

Ankylosing Spondylitis:
For the treatment of patients with active ankylosing spondylitis who have failed to respond to an adequate trial of at least three different nonsteroidal anti-inflammatory drugs (NSAIDs) and, in patients with peripheral joint involvement, have failed to respond to methotrexate or sulfasalazine.

Request for coverage must be made by a specialist in rheumatology.

Psoriasis:
For treatment of adult patients with severe plaque psoriasis presently with one or more of the following:
• Psoriasis Area and the Severity Index (PASI) ≥ 10
• Body Surface Area (BSA) > 10%
• Significant involvement of the face, hands feet or genital region
• Dermatology Life Quality Index (DLQI) > 10 AND
• Failure to respond to, contraindications to, intolerant of or unable to access methotrexate, cyclosporine and/or phototherapy.

Coverage will be approved initially for a maximum of 3 months. For continued coverage the physician must confirm the patient's response to treatment and demonstration of treatment clinical benefits:
• ≥ 50% reduction in the PASI score with ≥ 5 point improvement in the DLQI
• ≥ 75 % reduction in the PASI score
• ≥ 50% reduction in the BSA with significant improvement of the face, hands, feet or genital region.

Request for coverage must be made by a specialist in dermatology.

02258595	**Humira**	adalimumab	40 mg/0.8 mL	Injection

Crohn's Disease:
For treatment of moderate to severely active Crohn's Disease and/or Fistulizing Crohn's Disease in patients refractory or with contraindications to an adequate course of 5-aminosalicyclic acid and corticosteroids and other immunosuppressive therapy.

Request for coverage must be made by a specialist in gastroenterology.

Rheumatoid Arthritis:
For treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARD's must also be tried.
Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

Request for coverage must be made by a specialist in rheumatology.

Psoriatic Arthritis:
For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARD's must also be tried.
Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

Request for coverage must be made by a specialist in rheumatology.

Ankylosing Spondylitis:
For the treatment of patients with active ankylosing spondylitis who have failed to respond to an adequate trial of at least three different nonsteroidal anti-inflammatory drugs (NSAIDs) and, in patients with peripheral joint involvement, who have failed to respond to methotrexate or sulfasalazine.

Request for coverage must be made by a specialist in rheumatology.

Psoriasis:
For treatment of adult patients with severe plaque psoriasis presently with one or more of the following:
• Psoriasis Area and the Severity Index (PASI) ≥ 10
• Body Surface Area (BSA) > 10%
• Significant involvement of the face, hands feet or genital region
• Dermatology Life Quality Index (DLQI) > 10 AND
• Failure to respond to, contraindications to, intolerant of or unable to access methotrexate, cyclosporine and/or phototherapy.

Coverage will be approved initially for a maximum of 4 months. For continued coverage the physician must confirm the patient's response to treatment and demonstration of treatment clinical benefits:
• ≥ 50% reduction in the PASI score with ≥ 5 point improvement in the DLQI
• ≥ 75 % reduction in the PASI score
• ≥ 50% reduction in the BSA with significant improvement of the face, hands, feet or genital region.

Request for coverage must be made by a specialist in dermatology.

02245913	**Kineret**	anakinra	150 mg/mL	Injection

Rheumatoid Arthritis:
For treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARD's must also be tried.
Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

Request for coverage must be by a specialist in rheumatology.

02244016	**Remicade**	infliximab	100 mg/10 mL	Injection

Crohn's Diease
For the treatment of moderate to severly active Crohn's Disease and/or Fistulating Crohn's Disease in patients refractory or with contraindications to an adequate course of 5-aminosalicyclic acid and corticosteroids and/or other immunosuppressive therapy.

Request for coverage must be made by a physician who is a specialist in gastroenterology.

Rheumatoid Arthritis
For the treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joins, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

Request for coverage must be made by a physician who is a specialist in rheumatology.

Psociatic Arthritis
For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindication to these agents is documented. One combination therapy of DMARD must also be tried. Initial application information should include information on disease activity such as the number of tender joins, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

Request for coverage must be made by a physician who is a specialist in rheumatology.

Ankylosing Spondylitis
For the treatment of patients with active ankylosing spondylitis who have failed to respond to an adequate trial of at least three different non-steroidal anti-inflammatory drugs (NSAIDs) and, in patients with peripheral joint involvement, have failed to respond to methotrexate or sulfasalazine.

Request for coverage must be made by a physician who is a specialist in rheumatology.

Psoriasis
For the treatment of adult patients with severe plaque psoriasis with one or more of the following:
- Psoriasis Area and Severity Index (PASI) ≥ 10;
- Body Surface Area (BSA) > 10 percent;
- Dermatology Life Quality Index (DLQI) > 10;
- Significant involvement of the face, hands, feet or genital region; AND
- Failure to respond to, contraindications to, intolerant of or unable to access methotrexate, cyclosporine and/or phototherapy.

The initial request is approved for a maximum of 4 months. For continued coverage the physician must confirm the patient's response to treatment and demonstration of treatment clinical benefits:
≥ 50 percent reduction in the PASI score with ≥ point improvement in the DLQI; OR
≥ 75 percent reduction in the PASI score; OR
≥ 50 percent reduction in the BSA with significant improvement of the face, hands, feet or genital region.

Request for coverage must be made by a physician who is a specialist in dermatology.

Ulcerative Colitis
For the treatment of patients with moderately to severly active ulcerative colitis who have had an inadequate response to conventional therapy including 5-aminosalicylate compounds, corticosteroids and immunomodulators.

Request for coverage must be made by a physician who is a specialist in gastroenterology.

02241927	**Rituxan**	rituximab	10 mg/mL	Injection

Rheumatoid Arthritis:
For the treatment of severely active rheumatoid arthritis (RA), in combination with methotrexate, for patients who have failed to respond to an adequate trial of one or more anti-tumor necrosis factor (anti-TNF) agents (monoclonal antibody OR fusion protein) OR who are contraindicated to anti-TNF agents.

Request for coverage must be made by a specialist in rheumatology.

02350092 02350106 02350114	**Actemra**	tocilizumab	80 mg/4 mL 200 mg/10 mL 400 mg/20 mL	Injection

Rheumatoid Arthritis:
For the treatment of adult patients who have moderate to severe active rheumatoid arthritis and who:
(i) failed treatment with at least 3 DMARD (disease-modifying antirheumatic drugs) therapies, one of which therapies must be either methotrexate or leflunomide, unless intolerance or contraindication to these therapies is documented; and
(ii) previously tried at least one combination of DMARD therapies.

Request for coverage must be made by a physician who is a specialist in rheumatology.

02237770	**Avonex**	interferon beta 1-a	30 mcg	Injection
02269201	**Avonex**	interferon beta 1-a	30 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
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
02249669 02249685	**Pamidronate Disodium Omega**	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.

02352559 02352567	**Apo-Mycophenolate**	mycophenolate mofetil	250 mg 500 mg	Capsules Tablets
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
02379996	**CO Mycophenolate**	mycophenolate mofetil	500 mg	Tablets
02371154 02370549	**Mylan-Mycophenolate**	mycophenolate mofetil	250 mg 500 mg	Capsules Tablets
02320630 02313855	**Sandoz Mycophenolate**	mycophenolate mofetil	250 mg 500 mg	Capsules Tablets
02364883 02348675	**Teva-Mycophenolate**	mycophenolate mofetil	250 mg 500 mg	Capsules 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	Tablets
02319225 02319233	**Mylan-Leflunomide**	leflunomide	10 mg 20 mg	Tablets
02241888 02241889	**Arava**	leflunomide	10 mg 20 mg	Tablets
02261251 02261278	**Novo-Leflunomide**	leflunomide	10 mg 20 mg	Tablets

02288265 02288273	**pms-Leflunomide**	leflunomide	10 mg 20 mg	Tablets
02283964 02283972	**Sandoz Leflunomide**	leflunomide	10 mg 20 mg	Tablets

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

02233542	**Diane-35**	cyproterone acetate/ ethinyl estradiol	2 mg/0.035 mg	Tablets
02290308	**Cyestra-35**	cyproterone acetate/ ethinyl estradiol	2 mg/0.035 mg	Tablets
02309556	**Novo-Cyproterone/Ethinyl Estradiol**	cyproterone acetate/ ethinyl estradiol	2 mg/0.035 mg	Tablets

(a)Treatment of severe refractory acne (e.g. birth control pills, topicals - vitamin A / acid gel, tretinoins, Accutane, antibiotics).
(b)Hirsutism not responding to standard therapy (e.g. birth control pills, spironolactone, metformin).

01968017	**Neupogen**	filgrastim	0.3 mg/mL	Injection

For the use in patients with HIV infection for the prevention and treatment of neutropenia to maintain a normal absolute neutrophil count (ANC).