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.

CHANGES TO APPROVAL PROCESS AND EXPIRY DATES - EFFECTIVE OCTOBER 2017

Effective October 1, 2017 many Part 3 drugs will no longer require EDS renewal for coverage under Manitoba's Provincial Drug Programs (PDP) and the Employment and Income Assistance Drug Program (EIA). All Part 3 EDS drugs will still require initial approval, but for many drugs, if coverage approval is granted, this approval will be indefinite and prescribers will no longer need to reapply for extending or renewing this coverage. Any patient that has an active EDS approval (as of October 1, 2017) for any of the drugs affected by this change will automatically have the approval extended indefinitely. This change will affect only products identified on the List of Designated Drugs and may be updated from time to time. Details can be found online at:
http://www.gov.mb.ca/health/pharmacare/profdocs/list_designated_eds.pdf

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.

EDS request forms are now available online, please visit:
http://www.gov.mb.ca/health/pharmacare/healthprofessionals.html#b

NOTES REGARDING THE EXCEPTION DRUG STATUS (EDS) PROGRAM:

- Duly licensed practitioners prescribing within their scope of practice may apply for EDS.
- Requests can be submitted by mail or by fax.

The fax number is (204) 942-2030 or 1-877-208-3588. These numbers are for health professionals only.

- To ensure eligible benefit coverage, approval must take place prior to purchase or dispensing of a prescription drug. Retroactive coverage is not provided, no exceptions.
- 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 one to two business days.
Urgent requests received during regular business hours will usually be processed within 24 hours.

- 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.
- For NEW requests - If a client meets Part 3 EDS criteria for one of the products identified in the List of Designated Drugs with Indefinite EDS Approval, benefit coverage will be granted indefinitely. The client will receive an initial approval letter which confirms indefinite EDS approval.
- For RENEWAL requests - If a client has an active EDS approval for a product identified in the List of Designated Drugs with Indefinite EDS Approval – as of October 1, 2017, this coverage will be grandfathered indefinitely; no renewal will be required. The client will not be sent a letter to confirm their continued EDS approval.
- If the request for benefit coverage is not approved, 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.

NOTE: Some private and extended health insurance providers require their clients to have the EDS approval before they agree to cover any part of the prescription cost. It is the clients' responsibility to contact their private drug plan directly for further information.

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 Manitoba Drug Formulary Review Process, please visit:
http://www.gov.mb.ca/health/mdbif/review.html

For more information on the Manitoba Drug Benefits and Interchangeability Formulary, please visit:
http://www.gov.mb.ca/health/mdbif/

PROVINCIAL DRUG PROGRAMS REVIEW PROCESS (SPECIAL CIRCUMSTANCES):

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

Provincial Drug Programs Review Committee
300 Carlton Street – Room 1015
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.

ANTIHYPERTENSIVE/ANTILIPIDEMIC DRUGS

02411253 02411261 02411288 02411296 02411318 02411326 02411334 02411342	**Apo-Amlodipine/ Atorvastatin**	amlodipine/atorvastatin	5/10 mg 5/20 mg 5/40 mg 5/80 mg 10/10 mg 10/20 mg 10/40 mg 10/80 mg	Tablet
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	Tablet
02362759 02362767 02362775 02362783 02362791 02362805 02362813 02362821	**GD-Amlodipine/ Atorvastatin**	amlodipine/atorvastatin	5/10 mg 5/20 mg 5/40 mg 5/80 mg 10/10 mg 10/20 mg 10/40 mg 10/80 mg	Tablet

02404222 02404230 02404249 02404257	**pms-Amlodipine/ Atorvastatin**	amlodipine/atorvastatin	5/10 mg 5/20 mg 10/10 mg 10/20 mg	Tablet

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.

AUTONOMIC DRUGS

02336715 02336723 02336731 02336758	**Apo-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02401614 02401622 02401630 02401649	**Med-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Tablet
02406985 02406993 02407000 02407019	**Mint-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Tablet
02242115 02242116 02242117 02242118	**Exelon**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02245240	**Exelon**	rivastigmine	2 mg/mL	Oral Liquid
02332809 02332817 02332825 02332833	**Mylan-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02305984 02305992 02306018 02306026	**Novo-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02306034 02306042 02306050 02036069	**pms-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02311283 02311291 02311305 02311313	**ratio-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02324563 02324571 02324598 02324601	**Sandoz Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule

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.

02423596	**Incruse Ellipta**	umeclidinium	62.5 mcg	Inhaler
02394936	**Seebri Breezehaler**	glycopyrronium	50 mcg	Powder for Inhalation
02246793	**Spiriva**	tiotropium	18 mcg	Capsule
02435381	**Spiriva Respimat**	tiotropium	2.5 mcg/dose	Inhaler
02409720	**Tudorza Genuair**	aclidinium	400 mcg	Inhaler

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

02418401	**Anoro Ellipta**	umeclidinium/vilanterol	62.5/25 mcg	Powder for Inhalation
02439530	**Duaklir Genuair**	aclidinium/formoterol	400 mcg/12 mcg	Inhaler
02441888	**Inspiolto Respimat**	olodaterol/tiotropium	2.5 mcg/2.5 mcg	Inhaler
02418282	**Ultibro Breezhaler**	indacterol/glycopyrronium	110/50 mcg	Inhaler

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

Note: Should not be used in combination with another LAAC or LABA

BLOOD FORMING AND COAGULATION

02132621 02132656 02430789 02132648 02132664 02231171 02352680 02352648 02352672 02352656 02352664	**Fragmin**	dalteparin	2500 IU/0.2 mL 2500 IU/mL 3500 IU/0.28 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 02429462 02429470 02429489	**Innohep**	tinzaparin	2500 IU/0.25 mL 10000 IU/mL 10000 IU/0.5 mL 20000 IU/mL 18000 IU/0.9 mL 3500 IU/0.35 mL 4500 IU/0.45 mL 14000 IU/0.7 mL 8,000/0.4 mL 12,000/0.6 mL 16,000/0.8 mL	Injection
02012472 02236883 02242692 02236564 02378426 02378434 02378442 02378469	**Lovenox**	enoxaparin	30 mg/0.3 mL 40 mg/0.4 mL 120 mg/0.8 mL 300 mg/3 mL 60 mg/0.6 mL 80 mg/0.8 mL 100 mg/mL 150 mg/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.

02378604 02378612	**Xarelto**	rivaroxaban	15 mg 20 mg	Tablet

For the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) for a duration of up to six months.

Exclusions:

▫ Patients with clinically significant active bleeding, such as gastrointestinal bleeding, including that associated with hemorrhagic manifestations, bleeding diathesis, spontaneous impairment of hemostasis or patients with spontaneous impairment of hemostasis.

▫ Patients with severe renal impairment (CrCl < 30 mL/min).

02377233 02397714	**Eliquis**	apixaban	2.5 mg 5 mg	Tablet
02458640 02458659 02458667	**Lixiana**	edoxaban	15 mg 30 mg 60 mg	Tablet
02312441 02358808	**Pradaxa**	dabigatran	110 mg 150 mg	Capsule
02378604 02378612	**Xarelto**	rivaroxaban	15 mg 20 mg	Tablet

At-risk patients with non-valvular atrial fibrillation for the prevention 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 labratory, clinic, pharmacy, and at home).

02377233	**Eliquis**	apixaban	2.5 mg	Tablet

For the prophylaxis of venous thromboembolism (VTE) following elective total hip replacement surgery or elective total knee replacement surgery, where the initial post-operative doses are administered in an acute care (hospital) setting.

02377233 02397714	**Eliquis**	apixaban	2.5 mg 5 mg	Tablet
02458640 02458659 02458667	**Lixiana**	edoxaban	15 mg 30 mg 60 mg	Tablet

For the treatment of venous thromboembolic events (VTE) (deep vein thrombosis [DVT] and pulmonary embolism [PE]), and the prevention of recurrent DVT and PE for a duration of up to six months.

CENTRAL NERVOUS SYSTEM AGENTS

Anorexigenic Agents and Respiratory and Cerebral Stimulants

02239665	**Alertec**	modafinil	100 mg	Tablet
02285398	**Apo-Modafinil**	modafinil	100 mg	Tablet
02430487	**Auro-Modafinil**	modafinil	100 mg	Tablet
02432560	**Mar-Modafinil**	modafinil	100 mg	Tablet
02420260	**Teva-Modafinil**	modafinil	100 mg	Tablet

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	Tablet
02242067 02242068 02242069	**Trileptal**	oxcarbazepine	150 mg 300 mg 600 mg	Tablet
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	Tablet
02285924 02285932 02285940	**Apo-Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablet
02375249 02375257 02375265	**Auro-Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablet
02274183 02274191 02274205	**CO Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablet

02403005 02403021 02403048	**Jamp-Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablet
02399776 02399784 02399792	**Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablet
02353342 02353350 02353369	**Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablet
02454653 02454661 02454688	**Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablet
02442531 02442558 02442566	**Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablet
02296101 02296128 02296136	**pms-Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablet
02440202 02440210 02440229	**NAT-Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablet
02396106 02396114 02396122	**Ran-Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablet
02461986 02461994 02462001	**Sandoz Levetiracetam**	levetiracetam	250 mg 500 mg 750 mg	Tablet

As an add-on anticonvulsant or for control of pain where initiated by a pain clinic and where other similar agents have failed e.g. gabapentin, lamotrigine, valproic acid, or topiramate.

02426862 02426870 02426889 02426897	**Aptiom**	eslicarbazepine	200 mg 400 mg 600 mg 800 mg	Tablet
02452936 02452944 02452952 02452960 02452979	**Brivlera**	brivaracetam	10 mg 25 mg 50 mg 75 mg 100 mg	Tablet
02404516 02404524 02404532 02404540 02404559 02404567	**Fycompa**	perampanel	2 mg 4 mg 6 mg 8 mg 10 mg 12 mg	Tablet
02357615 02357623 02357631 02357658	**Vimpat**	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet

For use as an adjunctive therapy in patients in the management of refractory partial-onset seizures (POS) in adult patients with epilepsy who are not satisfactorily controlled with conventional therapy and who meet all of the following criteria:
(a) are under the care of a physician experienced in the treatment of epilepsy,
(b) are currently receiving two or more antiepileptic drugs, and
(c) in whom all other antiepileptic drugs are ineffective or not appropriate

Non-Steroidal Anti-Inflammatory Agents				
02248973 02248974	**Apo-Meloxicam**	meloxicam	7.5 mg 15 mg	Tablet
02390884 02390892	**Auro-Meloxicam**	meloxicam	7.5 mg 15 mg	Tablet
02250012 02250020	**CO Meloxicam**	meloxicam	7.5 mg 15 mg	Tablet
02353148 02353156	**Meloxicam**	meloxicam	7.5 mg 15 mg	Tablet
02255987 02255995	**Mylan-Meloxicam**	meloxicam	7.5 mg 15 mg	Tablet
02242785 02242786	**Mobicox**	meloxicam	7.5 mg 15 mg	Tablet
02258315 02258323	**Teva-Meloxicam**	meloxicam	7.5 mg 15 mg	Tablet
02248267 02248268	**pms-Meloxicam**	meloxicam	7.5 mg 15 mg	Tablet
02247889 02248031	**ratio-Meloxicam**	meloxicam	7.5 mg 15 mg	Tablet

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 spondylitis, 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 Tablet

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	Tablet
02319977 02319985 02319993	**pms-Oxycodone**	oxycondone HCl	5 mg 10 mg 20 mg	Tablet
00789739 00443948 02262983	**Supeudol**	oxycodone HCl	5 mg 10 mg 20 mg	Tablet
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 Tablet

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				
02420864 02420872	**Abilify Maintena**	aripiprazole	300 mg/vL 400 mg/vL	Injection
02354217 02354225 02354233 02354241	**Invega Sustenna**	paliperidone	50 mg/0.5 mL 75 mg/0.75 mL 100 mg/mL 150 mg/1.5 mL	Injection
02455943 02455986 02455994 02456001	**Invega Trinza**	paliperidone	175 mg/0.875 mL 263 mg/1.315 mL 350 mg/1.75 mL 525 mg/2.625 mL	Injection
02298465 02255707 02255727 02255758	**Risperdal Consta**	risperidone	12.5 mg 25 mg 37.5 mg 50 mg	Injection

For patients with schizophrenia:
(a) With a history of non-adherence, as evidenced by outcomes such as repeated hospitalizations, or
(b) Who have tried one or more antipsychotic agents, and who continue to be inadequately controlled, or are experiencing significant side effects such as EPS.

NOTE: Invega Trinza to be used only after Invega Sustenna has been established as adequate treatment for at least four months.

ELECTROLYTIC, CALORIC AND WATER BALANCE

02242814	**Apo-Lactulose**	lactulose	667 mg/mL	Oral Liquid
02247383	**Euro-LAC**	lactulose	667 mg/mL	Oral Liquid
02295881	**Jamp-Lactulose**	lactulose	667 mg/mL	Oral Solution
02412268	**Lactulose**	lactulose	667 mg/mL	Oral Solution
00703486 02469391	**pms-Lactulose**	lactulose	667 mg/mL	Oral Liquid
00854409	**ratio-Lactulose**	lactulose	667 mg/mL	Oral Liquid

Portal systemic encephalopathy.

02410702	**Zaxine**	rifaximin	550 mg	Tablet

For reducing the risk of overt hepatic encephalopathy (HE) recurrence (i.e. 2 or more episodes), if the following clinical criteria are met:
(a) Patients are unable to achieve adequate control of HE recurrence with maximal tolerated dose of lactulose alone;
(b) Must be used in combination with a maximal tolerated dose of lactulose;
(c) For patients not maintained on lactulose, information is required regarding the nature of the patient's intolerance to lactulose.

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

02238525	**HP-Pac**	amoxicillin/clarithromycin/ lansoprazole	500 mg 500 mg 30 mg	Tablet

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

02212005	**Apo-Loperamide**	loperamide	2 mg	Tablet
02256452	**Jamp-Loperamide**	loperamide	2 mg	Tablet
02229552	**Diarr-eze**	loperamide	2 mg	Tablet
02183862	**Imodium**	loperamide	2 mg	Tablet
02132591	**Novo-Loperamide**	loperamide	2 mg	Tablet
02228351	**pms-Loperamide**	loperamide	2 mg	Tablet
02233998	**Rhoxal-loperamide**	loperamide	2 mg	Tablet
02257564	**Sandoz Loperamide**	loperamide	2 mg	Tablet

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	Capsule

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

02242572 02242573 02242574	**Actos**	pioglitazone	15 mg 30 mg 45 mg	Tablet
02303442 02303450 02303469	**Accel-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet
02302942 02302950 02302977	**Apo-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet

02384906 02384914 02384922	**Auro-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet
02302861 02302888 02302896	**CO Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet
02397307 02365529 02365537	**Jamp-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet
02298279 02298287 02298295	**Mylan-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet
02274914 02274922 02274930	**Novo-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet
02326477 02326485 02326493	**Mint-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet
02391600 02339587 02339595	**Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet
02303124 02303132 02303140	**pms-Pioglitazone**	pioglitazone	15 mg 30 mg 45 mg	Tablet
02375850 02375869 02375877	**Ran-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
02434121 02434148 02434156	**VAN-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: *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	Tablet
02295377 02295385 02295393	**Apo-Glimepiride**	glimepiride	1 mg 2 mg 4 mg	Tablet
02274248 02274272 02274256	**CO Glimepiride**	glimepiride	1 mg 2 mg 4 mg	Tablet
02273756 02273764 02273772	**Novo-Glimepiride**	glimepiride	1 mg 2 mg 4 mg	Tablet
02273101 02273128 02273136	**ratio-Glimepiride**	glimepiride	1 mg 2 mg 4 mg	Tablet
02269589 02269597 02269619	**Sandoz Glimepiride**	glimepiride	1 mg 2 mg 4 mg	Tablet

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	Tablet
02424258 02424266 02424274	**Auro-Repaglinide**	repaglinide	0.5 mg 1 mg 2 mg	Tablet
02321475 02321483 02321491	**CO Repaglinide**	repaglinide	0.5 mg 1 mg 2 mg	Tablet
02239924 02239925 02239926	**Gluconorm**	repaglinide	0.5 mg 1 mg 2 mg	Tablet
02354926 02354934 02354942	**pms-Repaglinide**	repaglinide	0.5 mg 1 mg 2 mg	Tablet
02357453 02357461 02357488	**Sandoz Repaglinide**	repaglinide	0.5 mg 1 mg 2 mg	Tablet

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

02425483 02425491	**Invokana**	canagliflozin	100 mg 300 mg	Tablet
02388839 02388847 02303922	**Januvia**	sitagliptin	25 mg 50 mg 100 mg	Tablet
02443937 02443945	**Jardiance**	empagliflozin	10 mg 25 mg	Tablet
02375842 02333554	**Onglyza**	saxagliptin	2.5 mg 5 mg	Tablet
02370921	**Trajenta**	linagliptin	5 mg	Tablet

For the treatment of patients with type 2 diabetes who have previously been treated with metformin and a sulfonylurea. 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.

02443937 02443945	**Jardiance**	empagliflozin	10 mg 25 mg	Tablet

As an adjunct to diet, exercise, and standard care therapy to reduce the incidence of cardiovascular (CV) death in patients with type 2 diabetes mellitus (T2DM) and established cardiovascular disease who have inadequate glycemic control, if the following criteria are met:

- Patients have inadequate glycemic control despite an adequate trial of metformin
- Patients have established cardiovascular disease as defined* in the EMPA-REG OUTCOME trial.

***NOTE*: Established CV disease is defined on the basis of one of the following:**

- History of myocardial infarction (MI).
- Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status).
- Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within 12 months prior to selection.
- Last episode of unstable angina > 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease.
- History of ischemic or hemorrhagic stroke.
- Occlusive peripheral artery disease.

02456575 02456583 02456591 02456605 02456613 02456621	**Synjardy**	empagliflozin/metformin	5/500 mg 5/850 mg 5/1000 mg 12.5/500 mg 12.5/850 mg 12.5/1000 mg	Tablet

For type 2 diabetic patients who have been titrated to a stable combination, for a minimum of 3 months, of the separate components, metformin and empagliflozin.

NOTE: *Patients must meet EDS criteria for empagliflozin.*

02333856 02333864 02333872	**Janumet**	sitagliptin/metformin	50/500 mg 50/850 mg 50/1000 mg	Tablet
02416794	**Janumet XR**	sitagliptin/metformin	50/1000 mg	Tablet
02403250 02403269 02403277	**Jentadueto**	linagliptin/metformin	2.5/500 mg 2.5/850 mg 2.5/1000 mg	Tablet
02389169 02389177 02389185	**Komboglyze**	saxagliptin/metformin	2.5/500 mg 2.5/850 mg 2.5/1000 mg	Tablet
02449935 02449943	**Xigduo**	dapagliflozin/metformin	5/850 mg 5/1000 mg	Tablet

For type 2 diabetic patients who have been titrated to a stable combination, for a minimum of at least 3 months, of the separate components, Metformin and Linagliptin/Saxagliptin/ Sitagliptin/Dapagliflozin, and for whom insulin is not an option.

02435462 02435470	**Forxiga**	dapagliflozin	5 mg 10 mg	Tablet

For the treatment of patients with type 2 diabetes.
1. Added on to metformin for patients:
   (a) Who have inadequate glycemic control on metformin;
   (b) Who have a contraindication or intolerance to a sulfonylurea;
   (c) For whom insulin is not an option.
2. Added on to a sulfonylurea for patients
   (a) Who have inadequate glycemic control on a sulfonylurea;
   (b) Who have a contraindication or intolerance to metformin;
   (c) For whom insulin is not an option.

MISCELLANEOUS SKIN AND MUCOUS MEMBRANE AGENTS

02244148 02244149	**Protopic**	tacrolimus	0.1% 0.03%	Ointment

Second-line therapy for short and long-term intermittent-treatment of moderate to severe atopic dermatitis in non-immunocompromised patients, in whom the use of conventional topical corticosteroid therapies are deemed inadvisable because of potential risks, or who are not adequately responsive to or intolerant of conventional therapies.

Note: Both 0.03% and 0.1% for adults and only 0.03% for children aged 2 to 15 years.

02319012	**Dovobet Gel**	calcipotriol/betamethasone	50 mcg/0.5 mg/g	Gel

For the treatment of moderate to severe scalp psoriasis vulgaris and mild to moderate plaque psoriasis vulgaris on the body after failure of calcipotriol.

SMOOTH MUSCLE RELAXANTS

02254735	**Oxytrol**	oxybutynin	36 mg	Transdermal Patch
02275066	**Trosec**	trospium	20 mg	Tablet

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

MISCELLANEOUS THERAPEUTIC AGENTS

02242518 02246896	**Actonel**	risedronate	5 mg 35 mg	Tablet
02353687	**Apo-Risedronate**	risedronate	35 mg	Tablet
02406306	**Auro-Risedronate**	risedronate	35 mg	Tablet
02368552	**Jamp-Risedronate**	risedronate	35 mg	Tablet
02357984	**Mylan-Risedronate**	risedronate	35 mg	Tablet
02298376 02298392	**Novo-Risedronate**	risedronate	5 mg 35 mg	Tablet
02302209	**pms-Risedronate**	risedronate	35 mg	Tablet
02370255	**Risedronate**	risedronate	35 mg	Tablet
02411407	**Risedronate**	risedronate	35 mg	Tablet
02327295	**Sandoz Risedronate**	risedronate	35 mg	Tablet
02239028	**Evista**	raloxifene	60 mg	Tablet
02279215	**Apo-Raloxifene**	raloxifene	60 mg	Tablet
02358840	**CO Raloxifene**	raloxifene	60 mg	Tablet
02312298	**Novo-Raloxifene**	raloxifene	60 mg	Tablet
02358921	**pms-Raloxifene**	raloxifene	60 mg	Tablet
02352966	**Alendronate**	alendronate sodium	70 mg	Tablet
02299712	**Alendronate**	alendronate sodium	70 mg	Tablet
02381486 02381494	**Alendronate**	alendronate sodium	10 mg 70 mg	Tablet
02248728 02248730	**Apo-Alendronate**	alendronate sodium	10 mg 70 mg	Tablet
02388545 02388553	**Auro-Alendronate**	alendronate sodium	10 mg 70 mg	Tablet
02258110	**CO Alendronate**	alendronate sodium	70 mg	Tablet
02385031	**Jamp-Alendronate**	alendronate sodium	70 mg	Tablet
02394863 02394871	**Mint-Alendronate**	alendronate sodium	10 mg 70 mg	Tablet
02270129 02286335	**Mylan-Alendronate**	alendronate sodium	10 mg 70 mg	Tablet

02247373 02261715	**Teva-Alendronate**	alendronate sodium	10 mg 70 mg	Tablet
02273179	**pms-Alendronate**	alendronate sodium	70 mg	Tablet
02284006	**pms-Alendronate FC**	alendronate sodium	70 mg	Tablet
02384701 02384728	**Ran-Alendronate**	alendronate sodium	10 mg 70 mg	Tablet
02275279	**ratio-Alendronate**	alendronate sodium	70 mg	Tablet
02288087 02288109	**Sandoz Alendronate**	alendronate sodium	10 mg 70 mg	Tablet
02428725 02428733	**VAN-Alendronate**	alendronate sodium	10 mg 70 mg	Tablet

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

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

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

To increase bone mass in men or postmenopausal women with osteoporosis who are at a high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:
High fracture risk defined as either:
- moderate 10-year fracture risk (10% to 20%) as defined by either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC} tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture;
OR
- high 10-year fracture risk (≥ 20%) as defined by either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC} tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool.
AND
Contraindication to oral bisphosphonates.
Notes:
• Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year.
• Contraindication to oral bisphosphonates will be considered. Contraindications include renal impairment, hypersensitivity, and abnormalities of the esophagus (e.g. esophageal stricture or achalasia).

02269198	**Aclasta**	zoledronic acid	5 mg/100 mL	Injection
02415100	**Taro-Zoledronic Acid**	zoledronic acid	5 mg/100 mL	Injection
02422433	**Zoldronic Acid**	zoledronic acid	5 mg/100 mL	Injection
02408082	**Zoldronic Acid**	zoledronic acid	5 mg/100 mL	Injection

1. Paget's disease.
2. a) For female patients with post-menopausal osteoporosis (PMO) at high risk for fracture and satisfy at least two of the following three criteria:
(i) Age > 75 years;
(ii) A prior fragility fracture;
(iii) A bone mineral density (BMD) T-score ≤ -2.5; OR
b) Female patients with PMO with a serious intolerance to oral bisphosphonates or for whom 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).

02244324	**Apo-Cyclosporine**	cyclosporine	100 mg/mL	Solution
02237671 02150689 02150662 02150670	**Neoral**	cyclosporine	10 mg 25 mg 50 mg 100 mg	Capsule
02150697	**Neoral**	cyclosporine	100 mg/mL	Solution
02247073 02247074 02242821	**Rhoxal-cyclosporine**	cyclosporine	25 mg 50 mg 100 mg	Capsule

(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.*

02436841	**Entyvio**	vedolizumab	300 mg/vL	Injection

For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had an inadequate response to conventional therapy including 5-aminosalicylate compounds, corticosteroids and immunomodulators AND
For the treatment of patients over 18 years of age with moderate to severely 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 specialist in gastroenterology.

02402475 02282097	**Orencia**	abatacept	125 mg/mL 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 specialist in rheumatology.

02455323 02455331	**Brenzys**	etanercept	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 made by a specialist in rheumatology.

Brenzys or Erelzi will be the preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Rheumatoid Arthritis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients.

Patients will not be permitted to switch from Brenzys to another etanercept product or vice versa, if previously trialed and deemed unresponsive to therapy.

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.

Brenzys or Erelzi will be the preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Ankylosing Spondylitis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients.

Patients will not be permitted to switch from Brenzys to another etanercept product or vice versa, if previously trialed and deemed unresponsive to therapy.

02462869 02462877 02462850	**Erelzi**	etanercept	50 mg/mL 25mg/0.5mL 50mg/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 made by a specialist in rheumatology.

Erelzi or Brenzys will be the preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Rheumatoid Arthritis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients.

Patients will not be permitted to switch from Erelzi to another etanercept product or vice versa, if previously trialed and deemed unresponsive to therapy.

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.

Erelzi or Brenzys will be the preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Ankylosing Spondylitis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients.

Patients will not be permitted to switch from Erelzi to another etanercept product or vice versa, if previously trialed and deemed unresponsive to therapy.

Polyarticular Juvenile Idiopathic Arthritis:

For the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age or older who are intolerant to or have inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).

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

New requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi.

Patients will not be permitted to switch from Erelzi to another etanercept product or vice versa, if previously trialed and deemed unresponsive to therapy.

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 made by a specialist in rheumatology.

Brenzys or Erelzi will be the preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Rheumatoid Arthritis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients.

Patients will not be permitted to switch from Enbrel to another etanercept product or vice versa, if:
1. Previously trialed and deemed unresponsive to therapy.

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.

Brenzys or Erelzi will be the preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Ankylosing Spondylitis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients.

Patients will not be permitted to switch from Enbrel to another etanercept product or vice versa, if:
1. Previously trialed and deemed unresponsive to therapy.

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.

Polyarticular Juvenile Idiopathic Arthritis:
For the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who are intolerant to or have inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).

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

Ulcerative Colitis:
For the treatment of adult patients with moderately to severely active 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 specialist in gastroenterology.

Hidradenitis Suppurativa

For the treatment of adult patients with active moderate to severe hidradenitis suppurativa who have not responded to conventional therapy (including systemic antibiotics) and who meet all of the following:

• A total abscess and nodule count of 3 or greater
• Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
• An inadequate response to a 90-day trial of oral antibiotics
• Prescribed by a practitioner with expertise in the management of patients with HS

Note: Treatment with adalimumab should be discontinued if there is no improvement after 12 weeks of treatment

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 made by a specialist in rheumatology.

02470373	**Renflexis**	infliximab	100 mg	Injection

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 joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

Renflexis or Inflectra will be the preferred infliximab option for all infliximab-naïve patients prescribed an infliximab product for Rheumatoid Arthritis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.
Patients will not be permitted to switch from Renflexis or Inflectra to another infliximab product or vice versa, if:
1. Previously trialed and deemed unresponsive to therapy.

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 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 joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

Renflexis or Inflectra will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Psoriatic Arthritis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.
Patients will not be permitted to switch from Renflexis or Inflectra to another infliximab product or vice versa, if:
1. Previously trialed and deemed unresponsive to therapy.

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 sulfazalazine.

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

Renflexis or Inflectra will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Ankylosing Spondylitis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.
Patients will not be permitted to switch from Renflexis or Inflectra to another infliximab product or vice versa, if:
1. Previously trialed and deemed unresponsive to therapy.

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 ≥ 5 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 specialist in dermatology.

Renflesis or Inflectra will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Psoriasis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.
Patients will not be permitted to switch from Renflexis or Inflectra to another infliximab product or vice versa, if:
1. Previously trialed and deemed unresponsive to therapy.

Crohn's Disease
For the treatment of patients with moderate to severely 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.

For adults: Renflexis or Inflectra will be the preferred infliximab option for all infliximab-naïve adult patients prescribed an infliximab product for Crohn's Disease.

For pediatrics: Renflexis will be the preferred infliximab option for all infliximab-naïve pediatric patients prescribed an infliximab product for Crohn's Disease.

Preferred means the first infliximab product to be considered for reimbursement for infliximab-naïve patients. Patients will not be permitted to switch from Renflexis or Inflectra to another infliximab product or viceversa, if:
1. Previously trialed and deemed unresponsive to therapy.

Ulcerative Colitis
For the treatment of patients with moderately to severely 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 specialist in gastroenterology.

For adults: Renflexis or Inflectra will be the preferred infliximab option for all infliximab-naïve adult patients prescribed an infliximab product for Ulcerative Colitis.

For pediatrics: Renflexis will be the preferred infliximab option for all infliximab-naïve pediatric patients prescribed an infliximab product for Ulcerative Colitis.

Preferred means the first infliximab product to be considered for reimbursement for infliximab-naïve patients. Patients will not be permitted to switch from Renflexis or Inflectra to another infliximab product or vice versa, if:
1. Previously trialed and deemed unresponsive to therapy.

02419475	**Inflectra**	infliximab	100 mg/vL	Injection

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 joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

Inflectra or Renflexis will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Rheumatoid Arthritis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

Patients will not be permitted to switch from Inflectra to another infliximab product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

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 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 specialist in rheumatology.

Inflectra or Renflexis will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Psoriatic Arthritis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

Patients will not be permitted to switch from Inflectra to another infliximab product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

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 sulfazalazine.

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

Inflectra or Renflexis will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Ankylosing Spondylitis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

Patients will not be permitted to switch from Inflectra to another infliximab product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

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 specialist in dermatology.

Inflectra or Renflexis will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Psoriasis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

Patients will not be permitted to switch from Inflectra to another infliximab product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

Crohn's Disease
For the treatment of patients over 18 years of age with moderate to severely 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.

Inflectra or Renflexis will be the preferred infliximab option for all infliximab-naïve patients prescribed an infliximab product for Crohn's Disease. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naïve patients.

Patients will not be permitted to switch from Inflectra to another infliximab product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

Ulcerative Colitis
For the treatment of patients over 18 years of age with moderately to severely 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 specialist in gastroenterology.

Inflectra or Renflexis will be the preferred infliximab option for all infliximab-naïve patients prescribed an infliximab product for Ulcerative Colitis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naïve patients.

Patients will not be permitted to switch from Inflectra to another infliximab product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

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

Crohn's Disease

For the treatment of moderate to severely 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.

Inflectra will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Crohn's Disease. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

Patients will not be permitted to switch from Remicade to another infliximab product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

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 specialist in rheumatology.

Inflectra or Renflexis will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Rheumatoid Arthritis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

Patients will not be permitted to switch from Remicade to another infliximab product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

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 contraindication 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 joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

Inflectra or Renflexis will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab products for Psoriatic Arthritis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

Patients will not be permitted to switch from Remicade to another infliximab product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

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 specialist in rheumatology.

Inflectra or Renflexis will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Ankylosing Spondylitis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

Patients will not be permitted to switch from Remicade to another infliximab product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

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 ≥ 5 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 specialist in dermatology.

Inflectra or Renflexis will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Psoriasis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

Patients will not be permitted to switch from Remicade to another infliximab product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

Ulcerative Colitis
For the treatment of patients with moderately to severely 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 specialist in gastroenterology.

Inflectra will be the preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Ulcerative Colitis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

Patients will not be permitted to switch from Remicade to another infliximab product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

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.

As induction-remission therapy for patients with severely active Granulomatosis with Polyangitis (GPA) and Microscopic Polyangitis (MPA) in whom the use of cyclophosamide has failed; or the use of cyclophosamide is not appropriate.

02424770	**Actemra**	tocilizumab	162 mg/0.9 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 specialist in rheumatology.

Giant Cell Arteritis (GCA):
For treatment of Giant Cell Arteritis (GCA) in adult patients where the following criteria are met:
- At initiation of therapy, or with relapse, patients should be receiving prednisone.
- Duration of therapy with tocilizumab should be limited to 52 weeks per treatment course.

Patients should be under the care of a physician with the experience of diagnosis and management of GCA.

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 specialist in rheumatology.

Systemic Juvenile Idiopathic Arthritis:
For the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older who:
(i) have responded inadequately to previous therapy with one or more non steroidal anti-inflammatory drugs; and
(ii) who have responded inadequately to previous therapy with one or more systemic corticosteroids.

Polyarticular Juvenile Idiopathic Arthritis:
For the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who are intolerant to or have inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).

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

02324776 02324784	**Simponi**	golimumab	50 mcg/0.5 mL 50 mcg/0.5 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 DMARDs 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.

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.

Psoriatic Arthritis:
For the 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 DMARDs must also have been 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.

Ulcerative Colitis:
For the treatment of patients with moderately to severely 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 specialist in gastroenterology.

02417472	**Simponi IV**	golimumab	50 mg/4 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 DMARDs 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.

02331675	**Cimzia**	certolizumab	200 mg/mL	Injection
02465574	**Cimzia**	certolizumab	200 mg/mL	Autoinjector

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 specialist in rheumatology.

Psoriatic Arthritis:

For the 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 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 3 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 specialist in rheumatology.

02320673 02320681	**Stelara**	ustekinumab	45 mg/0.5 mL 90 mg/mL	Injection

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.

02438070	**Cosentyx**	secukinumab	150 mg/mL	Injection

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.

Psoriatic Arthritis (PsA):

For the 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 DMARDs 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 (AS):

For the treatment of patients with active ankylosing spondylitis who have failed to respond to an adequate trial of at least 3 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 specialist in rheumatology.

02455102 02455110	**Taltz**	ixekizumab	80 mg/mL 80 mg/mL	Autoinjector Pre-filled Syringe

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.

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

02473623	**Siliq**	brodalumab	210 mg/1.5 mL	Injection

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

02416328	**Aubagio**	teriflunomide	14 mg	Tablet
02237770	**Avonex**	interferon beta 1-a	30 mcg	Injection
02269201	**Avonex**	interferon beta 1-a	30 mcg/0.5 mL	Injection
02418320	**Lemtrada**	alemtuzumab	12 mg/1.2 mL	Solution for IV Infusion
02237319	**Rebif**	interferon beta 1-a	22 mcg/0.5 mL	Injection
02237320	**Rebif**	interferon beta 1-a	44 mcg/0.5 mL	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
02460661	**Glatect**	glatiramer acetate	20 mg	Pre-Filled Syringe
02365480	**Gilenya**	fingolimod	0.5 mg	Capsule
02444399 02444402	**Plegridy**	peginterferon beta-1a	125 mcg/0.5 mL 63 mcg.0.5 mL	Injection
02404508 02420201	**Tecfidera**	dimethyl fumarate	120 mg 240 mg	Capsule
02286386	**Tysabri**	natalizumab	300 mg/15 mL	Injection

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

Glatect will be the preferred glatiramer acetate option for all glatiramer acetate-naïve patients prescribed a glatiramer acetate product for relapsing-remitting multiple sclerosis (MS). Patients will not be permitted to switch from Glatect to another glatiramer acetate product or vice versa, if:

1. Previously trialed and deemed unresponsive to therapy.

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).

02296462 02296470 02331667 02296489	**Advagraf**	tacrolimus	0.5 mg 1 mg 3 mg 5 mg	Capsule

For the prophylaxis of organ rejection in patients receiving allogeneic liver or kidney transplants.

02243144 02175991 02175983	**Prograf**	tacrolimus	0.5 mg 1 mg 5 mg	Capsule
02176009	**Prograf**	tacrolimus	5 mg/mL	Injection
00960632	**Prograf**	tacrolimus	0.5 mg/ mL	Suspension
02416816 02416824 02416832	**Sandoz Tacrolimus**	tacrolimus	0.5 mg 1 mg 5 mg	Capsule

(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	Capsule Tablet
02192748 00960601	**Cellcept**	mycophenolate mofetil	250 mg 50 mg/mL	Capsule
02242145	**Cellcept**	mycophenolate mofetil	200 mg/mL	Injection
02237484	**Cellcept**	mycophenolate mofetil	500 mg	Tablet
02379996	**CO Mycophenolate**	mycophenolate mofetil	500 mg	Tablet
02386399 02380382	**Jamp-Mycophenolate**	mycophenolate mofetil	250 mg 500 mg	Capsule Tablet
02383780 02378574	**Mycophenolate**	mycophenolate mofetil	250 mg 500 mg	Capsule
02457369 02457377	**Mycophenolate**	mycophenolate mofetil	250 mg 500 mg	Capsule
02371154 02370549	**Mylan-Mycophenolate**	mycophenolate mofetil	250 mg 500 mg	Capsule Tablet
02320630 02313855	**Sandoz Mycophenolate**	mycophenolate mofetil	250 mg 500 mg	Capsule Tablet

02364883 02348675	**Teva-Mycophenolate**	mycophenolate mofetil	250 mg 500 mg	Capsule Tablet
02433680 02432625	**VAN-Mycophenolate**	mycophenolate mofetil	250 mg 500 mg	Capsule Tablet

(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.

02264560 02264579	**Myfortic**	mycophenolate sodium	180 mg 360 mg	Tablet
02372738 02372746	**Apo-Mycophenolic Acid**	mycophenolate sodium	180 mg 360 mg	Tablet

For the prophylaxis of organ rejection in patients receiving allogeneic renal transplants.

02248540	**Apo-Tryptophan**	l-tryptophan	500 mg	Capsule
02248538 02458721 02248539	**Apo-Tryptophan**	l-tryptophan	500 mg 750 mg 1 g	Tablet
02240445 02230202	**pms-Tryptophan**	l-tryptophan	500 mg 1 g	Tablet
02240334	**ratio-Tryptophan**	l-tryptophan	500 mg	Capsule
02240333 02237250	**ratio-Tryptophan**	l-tryptophan	500 mg 1 g	Tablet
00718149	**Tryptan**	l-tryptophan	500 mg	Capsule
02029456 00654531	**Tryptan**	l-tryptophan	500 mg 1 g	Tablet

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

02256495 02256509	**Apo-Leflunomide**	leflunomide	10 mg 20 mg	Tablet
02351668 02351676	**Leflunomide**	leflunomide	10 mg 20 mg	Tablet
02319225 02319233	**Mylan-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.

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

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

02408163	**Fibristal**	uliprostal	5 mg	Tablet

For the treatment of moderate to severe signs and symptoms of uterine fibroids in adult women of reproductive age, who are eligible for surgery under the following conditions:
(a) The duration of treatment will not exceed three (3) months, per patient, per lifetime;
(b) The patient is under the care of a physician experienced in the management of gynecological conditions such as uterine fibroids.

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).

Grastofil will be the preferred filgrastim option for all filgrastim-naive patients. Preferred means the first infliximab product to be considered for reimbursement for filgrastim-naive patients.

02441489	**Grastofil**	filgrastim	300 mcg/0.5 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).

Grastofil will be the preferred filgrastim option for all filgrastim-naive patients. Preferred means the first infliximab product to be considered for reimbursement for filgrastim-naive patients.

02387174	**Dificid**	fidaxomicin	200 mg	Tablet

For the treatment of patients:
(a) in place of vancomycin if there is a documented allergy to vancomycin; or
(b) as an alternative to vancomycin if a patient experiences a “severe adverse reaction” to vancomycin therapy; or
(c) treatment that results in the discontinuation of vancomycin;
(d) as an alternative to vancomycin if a patient experiences a 'severe intolerance' to vancomycin treatment that results in the discontinuation of vancomycin therapy; or
(e) for use in the event of vancomycin treatment failure.

In addition to the above, for use in prior Clostridium Difficile Infection (CDI) situations after other current CDI treatment options fail.

02393751	**Esbriet**	pirfenidone	267 mg	Capsule
02464489 02464500	**Esbriet**	pirfenidone	267 mg 801 mg	Tablet
02443066 02443074	**Ofev**	nintedanib	100 mg 150 mg	Capsule

For the treatment of adult patients who have a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF)* confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
*Mild-moderate IPF is defined as: forced vital capacity (FVC) greater than or equal to 50% of predicted.

02425696	**Firazyr**	icatibant	30 mg/3 mL	Pre-filled Syringe

For the treatment of acute attacks of hereditary Angioedema (HAE) in adults with lab confirmed c1-esterase inhibitor deficiency (type I or II) if the following conditions are met:
(a) Treatment of acute non-laryngeal attacks of at least moderate severity OR
(b) Treatment of acute laryngeal attacks,
(c) Limited to a single dose for self-administration AND
(d) Prescribed by an allergist with experience in the treatment of HAE AND
(e) Up to 2 doses on hand at any one time.