

## EXCEPTION DRUG STATUS (EDS)

Certain drugs or other items 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 or other items usually fall into one of the following categories:

- The drug or other item is ordinarily administered only to an in-patient of a hospital but is being administered outside of a hospital because of exceptional circumstances.
- The drug or other item is not ordinarily prescribed or administered in Manitoba, but is being prescribed because it is required in the treatment of a patient who has 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 the minister, supports a specific treatment regime that 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 client's Pharmacare deductible has been met.

**Effective October 18, 2021, "Part 3 Exception Drug Status" or "Part 3 benefits" will be referred to as "Exception Drug Status" or "EDS benefits".**

### **CHANGES TO APPROVAL PROCESS AND EXPIRY DATES - EFFECTIVE OCTOBER 2017**

Effective October 1, 2017 many 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 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:

<https://www.gov.mb.ca/health/pharmacare/healthprofessionals.html>

### **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 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 (CDR) 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 Health (CADTH). 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 Formulary and the Manitoba Drug Interchangeability Form

<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 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 1070  
 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	<b>Apo-Amlodipine/ Atorvastatin</b>	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	<b>Caduet</b>	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	<b>GD-Amlodipine/ Atorvastatin</b>	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

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	<b>Apo-Rivastigmine</b>	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02242115 02242116 02242117 02242118	<b>Exelon</b>	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02245240	<b>Exelon</b>	rivastigmine	2 mg/mL	Oral Liquid
02485362 02485370 02485389 02485397	<b>Jamp-Rivastigmine</b>	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02401614 02401622 02401630 02401649	<b>Med-Rivastigmine</b>	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Tablet
02324563 02324571 02324598 02324601	<b>Sandoz Rivastigmine</b>	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.

02501244	<b>Energair Breezhaler</b>	glycopyrronium/indacaterol/ mometasone furoate	50/150/160 mcg	Capsule	NVT
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For the treatment of asthma in adult patients inadequately controlled with a maintenance combination of a long-acting beta-2 agonist (LABA) and a medium or high dose of an inhaled corticosteroid (ICS), who have experienced one or more asthma exacerbations in the previous 12 months.

02474522	<b>Trelegy Ellipta</b>	fluticasone furoate/ umeclidinium/vilanterol	100 mcg/ 62.5 mcg/25 mg	Powder for Inhalation
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For the long-term, once daily, maintenance treatment of COPD, including chronic bronchitis and/or emphysema according to the following:

- Patients should not be started on triple inhaled therapy as initial therapy for COPD
- For use in patients who are not controlled on optimal dual inhaled therapy for COPD

## BLOOD FORMING AND COAGULATION

02132621 02430789 02132648 02132664 02231171 02352680 02352648 02352672 02352656 02352664	<b>Fragmin</b>	dalteparin	2500 IU/0.2 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	<b>Fraxiparine</b>	nadroparin	9500 IU/mL 19000 IU/mL	Injection
02229755 02167840 02231478 02229515 02358182 02358158 02358166 02358174 02429462 02429470 02429489	<b>Innohep</b>	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	<b>Lovenox</b>	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
02507501 02507528 02507536 02507544 02507552 02507560 02507579	<b>Inclunox</b> <i>(biosimilar)</i>	enoxaparin sodium	30 mg/0.3 mL 40 mg/0.4 mL 60 mg/0.6 mL 80 mg/0.8 mL 100 mg/1 mL 120 mg/0.8 mL 150 mg/1 mL	Injection

02507560 02507579	<b>Inclunox-HP</b> ( <i>biosimilar</i> )	enoxaparin sodium	120 mg/0.8 mL 150 mg/1 mL	Injection
02509075 02509083 02509091 02509105 02509113 02509121	<b>Redesca</b> ( <i>biosimilar</i> )	enoxaparin sodium	30 mg/0.3 mL 40 mg/0.4 mL 60 mg/0.6 mL 80 mg/0.8 mL 100 mg/mL 300 mg/3 mL	Injection
02509148 02509156	<b>Redesca HP</b> ( <i>biosimilar</i> )	enoxaparin sodium	120 mg/0.8 mL 150 mg/mL	Injection

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

Inclunox, Inclunox HP, Redesca or Redesca HP will be the preferred enoxaparin option for all enoxaparin-naïve patients prescribed enoxaparin. Preferred means the first enoxaparin product to be considered for reimbursement for enoxaparin-naïve patients. Patients will not be permitted to switch from Lovenox, Inclunox, Inclunox HP, Redesca or Redesca HP to another enoxaparin product or vice versa, if previously trialed and deemed unresponsive to therapy.

02316986	<b>Xarelto</b>	rivaroxaban	10 mg	Tablet
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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	<b>Xarelto</b>	rivaroxaban	15 mg 20 mg	Tablet
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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	<b>Eliquis</b>	apixaban	2.5 mg 5 mg	Tablet
02458640 02458659 02458667	<b>Lixiana</b>	edoxaban	15 mg 30 mg 60 mg	Tablet
02312441 02358808	<b>Pradaxa</b>	dabigatran	110 mg 150 mg	Capsule
02468913	<b>Apo-Dabigatran</b>	dabigatran	150 mg	Capsule
02378604 02378612	<b>Xarelto</b>	rivaroxaban	15 mg 20 mg	Tablet

For patients with non-valvular atrial fibrillation (AF) 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 laboratory, clinic, pharmacy, and at home).

02377233	<b>Eliquis</b>	apixaban	2.5 mg	Tablet
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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	<b>Eliquis</b>	apixaban	2.5 mg 5 mg	Tablet
02458640 02458659 02458667	<b>Lixiana</b>	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.

### **Iron Preparations**

02477777	<b>Monoferric</b>	iron	100 mg/mL	Injection
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For the treatment of iron deficiency anemia (IDA) in patients who meet the following criteria:

- Patient has a documented diagnosis of IDA based on laboratory test results (i.e. hemoglobin, ferritin); AND
- Patient has failed to respond or is intolerant to an adequate trial (at least 4 weeks) of oral iron therapy; OR
- Patient has a contraindication to oral iron therapy.
- Monoferric is administered in a setting where appropriate monitoring and management of hypersensitivity reactions can be provided to the patient.

02243716	<b>Venofer</b>	iron sucrose	20 mg/mL	Injectable Solution
02502917	<b>pms-Iron Sucrose</b>	iron sucrose	20 mg/mL	Injectable Solution

For the treatment of iron deficiency anemia (IDA) in patients who meet the following criteria:

- Patient has a documented diagnosis of IDA based on laboratory test results (i.e. hemoglobin, ferritin); AND
- Patient has failed to respond or is intolerant to an adequate trial (at least 4 weeks) of oral iron therapy; OR
- Patient has a contraindication to oral iron therapy.
- Iron sucrose is administered in a setting where appropriate monitoring and management of hypersensitivity reactions can be provided to the patient.

## CENTRAL NERVOUS SYSTEM AGENTS

### Anorexigenic Agents and Respiratory and Cerebral Stimulants

02239665	<b>Alertec</b>	modafinil	100 mg	Tablet
02285398	<b>Apo-Modafinil</b>	modafinil	100 mg	Tablet
02430487	<b>Auro-Modafinil</b>	modafinil	100 mg	Tablet
02503727	<b>Jamp Modafinil</b>	modafinil	100 mg	Tablet
02432560	<b>Mar-Modafinil</b>	modafinil	100 mg	Tablet
02420260	<b>Teva-Modafinil</b>	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.

02318024	<b>Apo-Atomoxetine</b>	atomoxetine	10 mg	Capsule
02318032			18 mg	
02318040			25 mg	
02318059			40 mg	
02318067			60 mg	
02445883	<b>Atomoxetine</b>	atomoxetine	10 mg	Capsule
02445905			18 mg	
02445913			25 mg	
02445948			40 mg	
02445956			60 mg	
02386410	<b>Sandoz Atomoxetine</b>	atomoxetine	10 mg	Capsule
02386429			18 mg	
02386437			25 mg	
02386445			40 mg	
02386453			60 mg	



02262800 02262819 02262827 02262835 02262843	<b>Strattera</b>	atomoxetine	10 mg 18 mg 25 mg 40 mg 60 mg	Capsule
02314541 02314568 02314576 02314584 02314592	<b>Teva-Atomoxetine</b>	atomoxetine	10 mg 18 mg 25 mg 40 mg 60 mg	Capsule

For treatment of Attention-Deficit Hyperactivity Disorder (ADHD) and must meet the following criteria:

- Patient has a contraindication or intolerance to, or has previously failed treatment with both of the following:

- a) one methylphenidate-based long-acting psychostimulant AND
- b) one amphetamine-based long-acting psychostimulant

<b>Anticonvulsants</b>				
02284294 02284308 02284316	<b>Apo-Oxcarbazepine</b>	oxcarbazepine	150 mg 300 mg 600 mg	Tablet
02242068 02242069	<b>Trileptal</b>	oxcarbazepine	300 mg 600 mg	Tablet
02244673	<b>Trileptal</b>	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.

02426862 02426870 02426889 02426897	<b>Aptiom</b>	eslicarbazepine	200 mg 400 mg 600 mg 800 mg	Tablet
02452936 02452944 02452952 02452960 02452979	<b>Brivlera</b>	brivaracetam	10 mg 25 mg 50 mg 75 mg 100 mg	Tablet
02357615 02357623 02357631 02357658	<b>Vimpat</b>	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02475332 02475340 02475359 02475367	<b>Auro-Lacosamide</b>	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet

02489287 02489295 02489309 02489317	<b>ACH-Lacosamide</b>	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02488388 02488396 02488418 02488426	<b>Jamp-Lacosamide</b>	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02512874 02512882 02512890 02512904	<b>Lacosamide (Sanis)</b>	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02487802 02487810 02487829 02487837	<b>Mar-Lacosamide</b>	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02490544 02490552 02490560 02490579	<b>Mint-Lacosamide</b>	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02499568 02499576 02499584 02499592	<b>NRA-Lacosamide</b>	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02478196 02478218 02478226 02478234	<b>Pharma-Lacosamide</b>	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02474670 02474689 02474697 02474700	<b>Sandoz Lacosamide</b>	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02472902 02472910 02472929 02472937	<b>Teva-Lacosamide</b>	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

02404516	<b>Fycompa</b>	perampanel	2 mg	Tablet
02404524			4 mg	
02404532			6 mg	
02404540			8 mg	
02404559			10 mg	
02404567			12 mg	

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

For use as an adjunctive therapy in the management of primary generalized tonic-clonic (PGTC) seizures 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

### Calcitonin Gene-related Peptide (CGRP) Antagonists

02497859 02509474	<b>Ajovy</b>	fremanezumab	225 mg/1.5 mL	Injection
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For the prevention of migraine in patients who have a confirmed diagnosis of either:

1. Episodic migraine: headaches for less than 15 days per month for more than 3 months of which at least 4 days per month are with migraine; OR
2. Chronic migraine: headaches for at least 15 days per month for more than 3 months of which at least 8 days per month are with migraine.

Initiation criteria:

- The patient must have experienced an inadequate response<sup>1</sup>, intolerance, or contraindication to at least two oral prophylactic migraine medications<sup>2</sup> of different classes; AND
- The patient must be under the care of a physician who has appropriate experience in the management of migraine headaches; AND
- The physician must provide the number of headache and migraine days per month at the time of initial request for reimbursement.

*Initial approval duration: 6 months*

Initial Renewal criteria:

- Reduction of at least 50% in the average number of migraine days per month compared with baseline.

*Renewal duration: 6 months*

Subsequent Renewal criteria:

- Maintenance of 50% reduction in the average number of migraine days per month from baseline.

<sup>1</sup> *Inadequate response to oral prophylactic therapies is defined as less than a 30% reduction in frequency of headache days to an adequate dose and duration of at least two prophylactic medications, which must be of a different class.*

<sup>2</sup> Oral prophylactic medication alternatives include:

- beta blockers
- tricyclic antidepressants
- verapamil or flunarizine
- sodium valproate or divalproex sodium
- topiramate
- gabapentin

Non-Steroidal Anti-Inflammatory Agents				
02248973 02248974	<b>Apo-Meloxicam</b>	meloxicam	7.5 mg 15 mg	Tablet
02390884 02390892	<b>Auro-Meloxicam</b>	meloxicam	7.5 mg 15 mg	Tablet
02353148 02353156	<b>Meloxicam (Sanis)</b>	meloxicam	7.5 mg 15 mg	Tablet
02248267 02248268	<b>pms-Meloxicam</b>	meloxicam	7.5 mg 15 mg	Tablet
02258315 02258323	<b>Teva-Meloxicam</b>	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	<b>Codeine Contin</b>	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	<b>Oxy-IR</b>	oxycodone HCl	5 mg 10 mg 20 mg	Tablet
02319977 02319985 02319993	<b>pms-Oxycodone</b>	oxycondone HCl	5 mg 10 mg 20 mg	Tablet
00789739 00443948 02262983	<b>Supeudol</b>	oxycodone HCl	5 mg 10 mg 20 mg	Tablet
00392480 00392472	<b>Supeudol</b>	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	<b>OxyNeo</b>	oxycodone	10 mg 15 mg 20 mg 30 mg 40 mg 60 mg 80 mg	Controlled Released Tablet
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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.

<b>Selective Serotonin and Norepinephrine Reuptake Inhibitors</b>				
02420864 02420872	<b>Abilify Maintena</b>	aripiprazole	300 mg/vL 400 mg/vL	Injection
02354217 02354225 02354233 02354241	<b>Invega Sustenna</b>	paliperidone	50 mg/0.5 mL 75 mg/0.75 mL 100 mg/mL 150 mg/1.5 mL	Injection
02455943 02455986 02455994 02456001	<b>Invega Trinza</b>	paliperidone	175 mg/0.875 mL 263 mg/1.315 mL 350 mg/1.75 mL 525 mg/2.625 mL	Injection

02298465 02255707 02255723 02255758	<b>Risperdal Consta</b>	risperidone	12.5 mg 25 mg 37.5 mg 50 mg	Injection
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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	<b>Apo-Lactulose</b>	lactulose	667 mg/mL	Oral Liquid
02295881	<b>Jamp-Lactulose</b>	lactulose	667 mg/mL	Oral Solution
02412268	<b>Lactulose</b>	lactulose	667 mg/mL	Oral Solution
02247383	<b>Pharma-Lactulose</b>	lactulose	667 mg/mL	Oral Liquid
00703486 02469391	<b>pms-Lactulose</b>	lactulose	667 mg/mL	Oral Liquid
00854409	<b>ratio-Lactulose</b>	lactulose	667 mg/mL	Oral Liquid

Portal systemic encephalopathy.

02410702	<b>Zaxine</b>	rifaximin	550 mg	Tablet
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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	<b>Alphagan P</b>	brimonidine tartrate	0.15%	Ophthalmic Solution
02301334	<b>Apo-Brimonidine P</b>	brimonidine tartrate	0.15%	Ophthalmic Solution

Intolerance to brimonidine 0.2%.

## GASTROINTESTINAL DRUGS

02470780	<b>Apo-Lansoprazole- Amoxicillin- Clarithromycin</b>	amoxicillin/clarithromycin/ lansoprazole	500 mg 500 mg 30 mg	Tablet
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For H. pylori Eradication (approved for a 7-14 day treatment course).

02256452	<b>Jamp-Loperamide</b>	loperamide	2 mg	Tablet
02132591	<b>Novo-Loperamide</b>	loperamide	2 mg	Tablet
02228351	<b>pms-Loperamide</b>	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	<b>Entocort</b>	budesonide	3 mg	Capsule
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**Crohn's Disease** of ileum, ascending colon (right-sided disease).

02391600 02339587 02339595	<b>ACH-Pioglitazone</b>	pioglitazone	15 mg 30 mg 45 mg	Tablet
02302861 02302888 02302896	<b>ACT Pioglitazone</b>	pioglitazone	15 mg 30 mg 45 mg	Tablet
02302942 02302950 02302977	<b>Apo-Pioglitazone</b>	pioglitazone	15 mg 30 mg 45 mg	Tablet
02397307 02365529 02365537	<b>Jamp-Pioglitazone</b>	pioglitazone	15 mg 30 mg 45 mg	Tablet
02326477 02326485 02326493	<b>Mint-Pioglitazone</b>	pioglitazone	15 mg 30 mg 45 mg	Tablet
02303124 02303132 02303140	<b>pms-Pioglitazone</b>	pioglitazone	15 mg 30 mg 45 mg	Tablet

02297906 02297914 02297922	<b>Sandoz Pioglitazone</b>	pioglitazone	15 mg 30 mg 45 mg	Tablet
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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.

02269589 02269597 02269619	<b>Sandoz Glimepiride</b>	glimepiride	1 mg 2 mg 4 mg	Tablet
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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.)

02321475 02321483 02321491	<b>ACT Repaglinide</b>	repaglinide	0.5 mg 1 mg 2 mg	Tablet
02424258 02424266 02424274	<b>Auro-Repaglinide</b>	repaglinide	0.5 mg 1 mg 2 mg	Tablet
02239924 02239925 02239926	<b>Gluconorm</b>	repaglinide	0.5 mg 1 mg 2 mg	Tablet
02354926 02354934 02354942	<b>Jamp-Repaglinide</b>	repaglinide	0.5 mg 1 mg 2 mg	Tablet
02357453 02357461 02357488	<b>Sandoz Repaglinide</b>	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	<b>Invokana</b>	canagliflozin	100 mg 300 mg	Tablet
02388839 02388847 02303922	<b>Januvia</b>	sitagliptin	25 mg 50 mg 100 mg	Tablet
02443937 02443945	<b>Jardiance</b>	empagliflozin	10 mg 25 mg	Tablet



02375842 02333554	<b>Onglyza</b>	saxagliptin	2.5 mg 5 mg	Tablet
02507471 02507498	<b>Apo-Saxagliptin</b>	saxagliptin	2.5 mg 5 mg	Tablet
02468603 02468611	<b>Sandoz Saxagliptin</b>	saxagliptin	2.5 mg 5 mg	Tablet
02370921	<b>Trajenta</b>	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	<b>Jardiance</b>	empagliflozin	10 mg 25 mg	Tablet
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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	<b>Synjardy</b>	empagliflozin/metformin	5/500 mg 5/850 mg 5/1000 mg 12.5/500 mg 12.5/850 mg 12.5/1000 mg	Tablet
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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	<b>Janumet</b>	sitagliptin/metformin	50/500 mg 50/850 mg 50/1000 mg	Tablet
02416794	<b>Janumet XR</b>	sitagliptin/metformin	50/1000 mg	Tablet

02403250 02403269 02403277	<b>Jentaducto</b>	linagliptin/metformin	2.5/500 mg 2.5/850 mg 2.5/1000 mg	Tablet
02389169 02389177 02389185	<b>Komboglyze</b>	saxagliptin/metformin	2.5/500 mg 2.5/850 mg 2.5/1000 mg	Tablet
02449935 02449943	<b>Xigduo</b>	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	<b>Forxiga</b>	dapagliflozin	5 mg 10 mg	Tablet
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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.

For adult patients with New York Heart Association (NYHA) class II and III heart failure, as an adjunct to standard of care therapy, for the treatment of heart failure with reduced ejection fraction (HFrEF) [Left ventricular ejection fraction (LVEF) < 40%]. Standard of care therapies include beta-blockers, angiotensin converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs), plus a mineralocorticoid receptor antagonist.

02471469 02471477	<b>Ozempic</b>	semaglutide	1.34 mg/mL	Injection
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For the treatment of type 2 diabetes in combination with metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control.

02464276 02464284	<b>Adlyxine</b>	lixisenatide	10 mcg 20 mcg	Injection
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For treatment of type 2 diabetes in combination with a basal insulin with or without metformin in patients who have been uncontrolled on, or are intolerant to, a sulfonylurea and metformin.

02478293	<b>Soliqua</b>	insulin glargine/lixisenatide	100 U/33 mcg	Injection
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For treatment of patients with type 2 diabetes who would be eligible for Adlyxine but will also be treated with a basal insulin (less than 60U/day) to achieve adequate glycemic control.

### **Glycogenolytic Agents**

02492415	<b>Baqsimi</b>	glucagon	3 mg	Powder
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For the treatment of severe hypoglycemia (SH) reactions in patients with diabetes mellitus who are receiving insulin therapy and are at high risk for SH, when impaired consciousness precludes oral

carbohydrates.

## MISCELLANEOUS SKIN AND MUCOUS MEMBRANE AGENTS

02244148 02244149	<b>Protopic</b>	tacrolimus	0.1% 0.03%	Ointment
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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.

02470365 02492504 02510049	<b>Dupixent</b>	dupilumab	150 mg/mL 200 mg/1.14 mL 150 mg/mL	Injection
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For the treatment of atopic dermatitis only if the following conditions are met;

### Initiation Criteria

- Patients aged 12 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- Patients must have had an adequate trial or be ineligible for each of the following therapies: phototherapy (where available), methotrexate, and cyclosporine.
- Patients who have had an adequate trial of phototherapy, methotrexate, and/or cyclosporine must have documented refractory disease or intolerance.
- The physician must provide the Eczema Area and Severity Index (EASI) score and Physician Global Assessment score at the time of initial request for reimbursement.
- The maximum duration of initial authorization is six months.

### Renewal Criteria

- The physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) six months after treatment initiation.
- The physician must provide proof of maintenance of EASI-75 response from baseline every six months for subsequent authorizations.

### Prescribing Conditions

- The patient must be under the care of a dermatologist.
- Dupilumab is not to be used in combination with phototherapy or immunosuppressant drugs, such as methotrexate or cyclosporine.

## SMOOTH MUSCLE RELAXANTS

02254735	<b>Oxytrol</b>	oxybutynin	36 mg	Transdermal Patch
02275066	<b>Trosec</b>	trospium	20 mg	Tablet
02488353	<b>Mar-Trospium</b>	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

02298384	<b>Novo-Risedronate</b>	risedronate	30 mg	Tablet
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For the treatment of **Paget's Disease**.

02343541	<b>Prolia</b>	denosumab	60 mg/mL	Injection
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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 ( $\geq 20\%$ ) 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	<b>Aclasta</b>	zoledronic acid	5 mg/100 mL	Injection
02415100	<b>Taro-Zoledronic Acid</b>	zoledronic acid	5 mg/100 mL	Injection
02422433	<b>Zoledronic Acid</b>	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  $\leq -2.5$ ; OR

b) Female patients with PMO with a serious intolerance to oral bisphosphonates or for whom oral bisphosphonates are contraindicated.

02368153	<b>Xgeva</b>	denosumab	120 mg	Injection
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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).

02237671 02150689 02150662 02150670	<b>Neoral</b>	cyclosporine	10 mg 25 mg 50 mg 100 mg	Capsule
02150697	<b>Neoral</b>	cyclosporine	100 mg/mL	Solution
02247073 02247074 02242821	<b>Sandoz Cyclosporine</b>	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	<b>Entyvio</b>	vedolizumab	300 mg/vL	Injection
02497875 02497867	<b>Entyvio SC</b>	vedolizumab	108 mg 108 mg	Pre-filled syringe Pre-filled pen

#### **Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

#### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

#### **Ulcerative Colitis**

For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

02402475 02282097	<b>Orencia</b>	abatacept	125 mg/mL 250 mg/vial	Injection
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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.*

02496933	<b>Avsola</b>	infliximab	100 mg/vial	Powder for Solution
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Avsola will be a preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Rheumatoid Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis, Psoriatic Arthritis, and Psoriasis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

### **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.*

***Avsola will be a 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 Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.***

### **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.*

***Avsola will be a 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 Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.***

### **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.*

***Avsola will be a 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 Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.***

### **Psoriasis**

For the treatment of adult patients with severe plaque psoriasis with one or more of the following:

- Psoriasis Area and Severity Index (PASI)  $\geq 10$ ;
- 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:

- $\geq 50$  percent reduction in the PASI score with  $\geq 5$  point improvement in the DLQI; OR
- $\geq 75$  percent reduction in the PASI score; OR
- $\geq 50$  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.*

***Avsola will be a 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 Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.***

### **Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

***For Adults: Avsola, Renflexis or Inflectra will be a preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Crohn's Disease.***

***For Pediatrics: Avsola will be a 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 Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.***

### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole)

AND

- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

**For Adults: Avsola will be a preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Fistulizing 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 Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.**

**Ulcerative Colitis**

For the treatment of patients with moderate to severely active ulcerative colitis who have had an inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

**For Adults: Avsola will be a preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Ulcerative Colitis.**

**For Pediatrics: Avsola will be a 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 Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.**

02455323 02455331	<b>Brenzys</b>	etanercept	50 mg/mL	Injection
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**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 will be a 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 etanercept.**

**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 will be a 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 etanercept.**



## **Psoriasis**

For the treatment of adult patients with severe plaque psoriasis presently with one or more of the following:

- Psoriasis Area and the Severity Index (PASI)  $\geq$  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:

- $\geq$  50% reduction in the PASI score with  $\geq$  5 point improvement in the DLQI
- $\geq$  75% reduction in the PASI score
- $\geq$  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.*

***Brenzys will be a preferred etanercept option for all etanercept-naive patients***

***prescribed an etanercept product for Psoriasis. 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 etanercept.***

## **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.*

***Brenzys will be a preferred etanercept option for all etanercept-naive patients weighing 63kg***

***(138 pounds) or more who are prescribed an etanercept product for Polyarticular Juvenile Idiopathic 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 etanercept.***

## **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.*

***Brenzys will be a preferred etanercept option for all etanercept-naive patients***

***prescribed an etanercept product for Psoriatic 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 etanercept.***

02462869 02462877 02462850	<b>Erelzi</b>	etanercept	50 mg/mL 25mg/0.5mL 50mg/mL	Injection
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### **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 will be a 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 etanercept.***

### **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 will be a 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 etanercept.***

### **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.*

***Erelzi will be a preferred etanercept option for all etanercept-naive patients weighing 63kg (138 pounds) or more who are prescribed an etanercept product for Polyarticular Juvenile Idiopathic 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 etanercept.***

### 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.*

***Erelzi will be a preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Psoriatic 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 etanercept.***

### 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)  $\geq 10$  □
- 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:

- $\geq 50\%$  reduction in the PASI score with  $\geq 5$  point improvement in the DLQI
- $\geq 75\%$  reduction in the PASI score
- $\geq 50\%$  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.*

***Erelzi will be a preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Psoriasis. 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 etanercept.***

02242903 02274728	<b>Enbrel</b>	etanercept	25 mg 50 mg/mL	Injection
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### 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 Enbrel, Erelzi or Brenzys to another etanercept product or vice versa, if previously trialed and deemed unresponsive to etanercept.***

### **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.*

***Erelzi or Brenzys will be the preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Psoriatic 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, Erelzi or Brenzys to another etanercept product or vice versa, if previously trialed and deemed unresponsive to etanercept.***

### **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 Enbrel, Erelzi or Brenzys to another etanercept product or vice versa, if previously trialed and deemed unresponsive to etanercept.***

### **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)  $\geq$  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:

- $\geq$  50% reduction in the PASI score with  $\geq$  5 point improvement in the DLQI
- $\geq$  75 % reduction in the PASI score
- $\geq$  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.*

***Erelzi or Brenzys will be the preferred etanercept option for all etanercept-naïve patients prescribed an etanercept product for Psoriasis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naïve patients.***

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

02474263	<b>Humira</b>	adalimumab	20 mg/0.2 mL	Injection
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**Pediatric Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

**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.*

02258595	<b>Humira</b>	adalimumab	40 mg/0.8 mL	Injection
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**Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

For Adults:

Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

For Pediatrics:

Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz or Idacio will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Humira, Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

**Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn's Disease. Preferred means the first adalimumab product to be considered for reimbursement

for adalimumab-naive patients. Patients will not be permitted to switch from Humira, Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Rheumatoid Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Humira, Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Humira, Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Humira, Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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)  $\geq 10$
- 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:

- $\geq 50\%$  reduction in the PASI score with  $\geq 5$  point improvement in the DLQI
- $\geq 75\%$  reduction in the PASI score
- $\geq 50\%$  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.*

Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriasis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab -naïve patients. Patients will not be permitted to switch from Humira, Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yulfyma will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab -naïve patients. Patients will not be permitted to switch from Humira, Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yulfyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Ulcerative Colitis**

For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Humira, Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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*

Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Humira, Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

02511061	<b>Abrilada</b>	adalimumab	20 mg/0.4 mL	Injection
02511053 02511045	<b>Abrilada</b>	adalimumab	40 mg/0.8 mL	Injection

### **Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

For Adults: Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

For Pediatrics: Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Abrilada to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Abrilada to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

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

Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Rheumatoid Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Abrilada to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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 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.*

Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Abrilada to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Abrilada to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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)  $\geq$  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:

- $\geq$  50% reduction in the PASI score with  $\geq$  5 point improvement in the DLQI
- $\geq$  75 % reduction in the PASI score

- $\geq 50\%$  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.*

Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriasis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Abrilada to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients.

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

- Previously trialed and deemed unresponsive to adalimumab.

### **Ulcerative Colitis**

For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Abrilada to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Abrilada to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

02459310 02459299 02459302	<b>Amgevita</b>	adalimumab	50 mg/mL	Injection
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### **Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

For Adults: Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

For Pediatrics: Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

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

Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Rheumatoid Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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 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.*

Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Ulcerative Colitis**

For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

02473097 02473100	<b>Hadlima</b>	adalimumab	40 mg/0.8 mL	Injection
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### **Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

For Adults: Hadlima will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hadlima to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

Hadlima will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hadlima to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

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

Hadlima will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Rheumatoid Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hadlima to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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 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.*

Hadlima will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hadlima to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Hadlima will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hadlima to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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)  $\geq 10$
- 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:

- $\geq 50\%$  reduction in the PASI score with  $\geq 5$  point improvement in the DLQI
- $\geq 75\%$  reduction in the PASI score

- $\geq 50\%$  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.*

Hadlima will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriasis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hadlima to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Hadlima will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients.

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

- Previously trialed and deemed unresponsive to adalimumab.

### **Ulcerative Colitis**

For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

Hadlima will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hadlima to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

Hadlima will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hadlima to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

02502380	<b>Hulio</b>	adalimumab	20 mg/0.4 mL	Injection
02502399 02502402	<b>Hulio</b>	adalimumab	40 mg/0.8 mL	Injection

### **Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

For Adults: Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

For Pediatrics: Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

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

Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Rheumatoid Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.



### **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 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.*

Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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)  $\geq 10$
- 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:

- $\geq 50\%$  reduction in the PASI score with  $\geq 5$  point improvement in the DLQI
- $\geq 75\%$  reduction in the PASI score
- $\geq 50\%$  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.*

Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriasis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Ulcerative Colitis**

For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

02492156	<b>Hyrimoz</b>	adalimumab	40 mg/0.8 mL	Injection
02492164			40 mg/0.8 mL	
02505258			20 mg/0.4 mL	

### **Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

For Adults: Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

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

Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Rheumatoid Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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 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.*

Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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)  $\geq 10$
- 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:

- $\geq 50\%$  reduction in the PASI score with  $\geq 5$  point improvement in the DLQI
- $\geq 75\%$  reduction in the PASI score
- $\geq 50\%$  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.*

Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriasis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### Ulcerative Colitis

For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### 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.

Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

02502674	<b>Idacio</b>	adalimumab	40 mg/0.8 mL	Injection
02502682	<b>Idacio</b>	adalimumab	40 mg/0.8 mL	Pre-filled Syringe

### Crohn's Disease

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

For Adults: Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

For Pediatrics: Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

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

Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Rheumatoid Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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 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.*

Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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)  $\geq 10$
- 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:

- $\geq 50\%$  reduction in the PASI score with  $\geq 5$  point improvement in the DLQI
- $\geq 75\%$  reduction in the PASI score
- $\geq 50\%$  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.*

Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriasis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Ulcerative Colitis**

For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to

be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

02523949 02523957	<b>Simlandi</b>	adalimumab	40 mg/0.4 mL	Injection
02523965	<b>Simlandi</b>	adalimumab	80 mg/0.8 mL	Injection

### **Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

For Adults: Simlandi will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Simlandi to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

Simlandi will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn's Disease.



Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Simlandi to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

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

Simlandi will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Rheumatoid Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Simlandi to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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 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.*

Simlandi will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Simlandi to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Simlandi will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Simlandi to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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)  $\geq 10$
- 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.*

Simlandi will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriasis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Simlandi to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Simlandi will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Simlandi to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Ulcerative Colitis**

For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

Simlandi will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Simlandi to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

Simlandi will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Simlandi to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

02523760 02523779	<b>Yuflyma</b>	adalimumab	40 mg/0.8 mL	Injection
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### **Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

For Adults: Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn's Disease.

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

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

Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Rheumatoid Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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 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.*

Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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)  $\geq 10$
- 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:

- $\geq 50\%$  reduction in the PASI score with  $\geq 5$  point improvement in the DLQI
- $\geq 75\%$  reduction in the PASI score
- $\geq 50\%$  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.*

Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriasis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.*

Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **Ulcerative Colitis**

For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

### **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.

Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:

- Previously trialed and deemed unresponsive to adalimumab.

02460521 02460548 02472961 02472988	<b>Kevzara</b>	sarilumab	150 mg/1.14 mL 200 mg/1.14 mL 150 mg/1.14 mL 200 mg/1.14 mL	Injection
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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 (disease modifying antirheumatic drug) 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.

02245913	<b>Kineret</b>	anakinra	150 mg/mL	Injection
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**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	<b>Renflexis</b>	infliximab	100 mg	Injection
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**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 will be a 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 Renflexis to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.***

**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 will be a 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 to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.***

### **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.*

***Renflexis will be a 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 to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.***

### **Psoriasis**

For the treatment of adult patients with severe plaque psoriasis with one or more of the following:

- Psoriasis Area and Severity Index (PASI)  $\geq$  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:

- $\geq$  50 percent reduction in the PASI score with  $\geq$  5 point improvement in the DLQI; OR
- $\geq$  75 percent reduction in the PASI score; OR
- $\geq$  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.*

***Renflexis will be a 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 to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.***

### **Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

***For Adults: Renflexis will be a preferred infliximab option for all infliximab-naive adult patients prescribed an infliximab product for Crohn's Disease.***  
***For Pediatrics: Renflexis will be a preferred infliximab option for all infliximab-naive pediatric 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 Renflexis to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.**

### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

**For Adults: Renflexis will be a preferred infliximab option for all infliximab-naive adult patients prescribed an infliximab product for Fistulizing Crohn's Disease.**

**For Pediatrics: Renflexis will be a preferred infliximab option for all infliximab-naive pediatric patients prescribed an infliximab product for Fistulizing 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 Renflexis to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.**

### **Ulcerative Colitis**

For the treatment of patients with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

**For Adults: Renflexis will be a preferred infliximab option for all infliximab-naive adult patients prescribed an infliximab product for Ulcerative Colitis.**

**For Pediatrics: Renflexis will be a preferred infliximab option for all infliximab-naive pediatric 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 Renflexis to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.**

02419475	<b>Inflectra</b>	infliximab	100 mg/vL	Injection
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### **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 will be a 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 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.*

***Inflectra will be a 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 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 will be a 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 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)  $\geq$  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:

- $\geq$  50 percent reduction in the PASI score with  $\geq$  point improvement in the DLQI; OR
- $\geq$  75 percent reduction in the PASI score; OR
- $\geq$  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 will be a preferred infliximab option for all infliximab-naïve patients prescribed an infliximab product for Psoriasis. 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 previously trialed and deemed unresponsive to therapy.***

### **Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

***For Adults: Inflectra will be a preferred infliximab option for all infliximab-naïve adult patients prescribed an infliximab product for Crohn's Disease.***

***For Pediatrics: Inflectra will be a 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 Inflectra to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.***

### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

***For Adults: Inflectra will be a preferred infliximab option for all infliximab-naïve adult patients prescribed an infliximab product for Fistulizing Crohn's Disease.***

***For Pediatrics: Inflectra will be a preferred infliximab option for all infliximab-naïve pediatric patients prescribed an infliximab product for Fistulizing 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 previously trialed and deemed unresponsive to therapy.***

### **Ulcerative Colitis**

For the treatment of patients with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

***For Adults: Inflectra will be a preferred infliximab option for all infliximab-naïve adult patients prescribed an infliximab product for Ulcerative Colitis.***

***For Pediatrics: Inflectra will be a 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 Inflectra to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.***

02244016	<b>Remicade</b>	infliximab	100 mg/10 mL	Injection
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### **Crohn's Disease**

For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

***For Adults: Renflexis, Inflectra or Avsola will be the preferred infliximab option for all infliximab-naive adult patients prescribed an infliximab product for Crohn's Disease.***

***For Pediatrics: Renflexis, Inflectra or Avsola will be the preferred infliximab option for all infliximab-naive 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 Remicade, Renflexis, Inflectra or Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.***

### **Fistulizing Crohn's Disease**

For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

***For Adults: Renflexis, Inflectra or Avsola will be the preferred infliximab option for all infliximab-naive adult patients prescribed an infliximab product for Fistulizing Crohn's Disease.***

***For Pediatrics: Renflexis, Inflectra or Avsola will be the preferred infliximab option for all infliximab-naive pediatric patients prescribed an infliximab product for Fistulizing 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 Remicade, Renflexis, Inflectra or Avsola to another infliximab product or vice versa, if 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 joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

***Renflexis, Inflectra or Avsola 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, Renflexis, Inflectra or Avsola to another infliximab product or vice versa, if 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.*

***Renflexis, Inflectra or Avsola 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 Remicade, Renflexis, Inflectra or Avsola to another infliximab 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 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.*

***Renflexis, Inflectra or Avsola 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, Renflexis, Inflectra or Avsola to another infliximab product or vice versa, if 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)  $\geq$  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:

$\geq$  50 percent reduction in the PASI score with  $\geq$  5 point improvement in the DLQI; OR

$\geq$  75 percent reduction in the PASI score; OR

$\geq$  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.*

***Renflexis, Inflectra or Avsola 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, Renflexis, Inflectra or Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.***

### Ulcerative Colitis

For the treatment of patients with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

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

***For Pediatrics: Renflexis, Inflectra or Avsola 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 Remicade, Renflexis, Inflectra or Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.***

02513447	Riabni	rituximab	10 mg/mL	Injection
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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 Polyangiitis (GPA) and Microscopic Polyangiitis (MPA) in whom:

- the use of cyclophosphamide has failed; or
- the use of cyclophosphamide is not appropriate

Riabni will be a preferred rituximab option for all rituximab-naïve patients prescribed a rituximab product for rheumatoid arthritis, Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA). Preferred means the first rituximab product to be considered for reimbursement for rituximab-naïve patients. Patients will not be permitted to switch from Riabni to another rituximab product or vice versa, if:

- Previously trialed and deemed unresponsive to therapy.

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

***Riabni, Riximyo, Ruxience or Truxima will be the preferred rituximab option for all rituximab-naïve patients prescribed a rituximab product for Rheumatoid Arthritis. Preferred means the first rituximab product to be considered for reimbursement for rituximab-naïve patients.***

***Patients will not be permitted to switch from Riabi, Rituxan, Riximyo, Ruxience or Truxima to another rituximab product or vice versa, if previously trialed and deemed unresponsive to therapy.***

### Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)

As induction-remission therapy for patients with severely active granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) in whom the cyclophosphamide has failed; or the use of cyclophosphamide is not appropriate.

***Riabni, Riximyo, Ruxience or Truxima will be the preferred rituximab option for all rituximab-naive patients prescribed a rituximab product for GPA and MPA. Preferred means the first rituximab product to be considered for reimbursement for rituximab-naive patients. Patients will not be permitted to switch from Riabni, Rituxan, Riximyo, Ruxience or Truxima to another rituximab product or vice versa, if previously trialed and deemed unresponsive to therapy.***

02498316	<b>Riximyo</b>	rituximab	10 mg/mL	Injection
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**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.*

***Riximyo will be a preferred rituximab option for all rituximab-naive patients prescribed a rituximab product for Rheumatoid Arthritis. Preferred means the first rituximab product to be considered for reimbursement for rituximab-naive patients. Patients will not be permitted to switch from Riximyo to another rituximab product or vice versa, if previously trialed and deemed unresponsive to therapy.***

**Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)**

As Induction-remission therapy for patients with severely active Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA) in whom:

- the use of cyclophosphamide has failed; or
- the use of cyclophosphamide is not appropriate

***Riximyo will be a preferred rituximab option for all rituximab-naive patients prescribed a rituximab product for GPA and MPA. Preferred means the first rituximab product to be considered for reimbursement for rituximab-naive patients. Patients will not be permitted to switch from Riximyo to another rituximab product or vice versa, if previously trialed and deemed unresponsive to therapy.***

02495724	<b>Ruxience</b>	rituximab	10 mg/mL	Injection
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**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.*

***Ruxience will be a preferred rituximab option for all rituximab-naive patients prescribed a rituximab product for Rheumatoid Arthritis. Preferred means the first rituximab product to be considered for reimbursement for rituximab-naive patients. Patients will not be permitted to switch from Ruxience to another rituximab product or vice versa, if previously trialed and deemed unresponsive to therapy.***

**Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)**

As Induction-remission therapy for patients with severely active Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA) in whom:

- the use of cyclophosphamide has failed; or
- the use of cyclophosphamide is not appropriate

***Ruxience will be a preferred rituximab option for all rituximab-naive***

*patients prescribed a rituximab product for GPA and MPA. Preferred means the first rituximab product to be considered for reimbursement for rituximab-naive patients. Patients will not be permitted to switch from Ruxience to another rituximab product or vice versa, if previously trialed and deemed unresponsive to therapy.*

02478382 02478390	<b>Truxima</b>	rituximab	100 mg/10 mL 500 mg/50 mL	Injection
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**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.*

***Truxima will be a preferred rituximab option for all rituximab-naive patients prescribed a rituximab product for Rheumatoid Arthritis. Preferred means the first rituximab product to be considered for reimbursement for rituximab-naive patients. Patients will not be permitted to switch from Truxima to another rituximab product or vice versa, if previously trialed and deemed unresponsive to therapy.***

**Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)**

As induction-remission therapy for patients with severely active granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) in whom:

- the use of cyclophosphamide has failed; or
- the use of cyclophosphamide is not appropriate

***Truxima will be a preferred rituximab option for all rituximab-naive patients prescribed a rituximab product for GPA and MPA. Preferred means the first rituximab product to be considered for reimbursement for rituximab-naive patients. Patients will not be permitted to switch from Truxima to another rituximab product or vice versa, if previously trialed and deemed unresponsive to therapy.***

02424770 02483327	<b>Actemra</b>	tocilizumab	162 mg/0.9 mL 162 mg/0.9 mL	Injection
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**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.*

**Giant Cell Arteritis**

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	<b>Actemra</b>	tocilizumab	80 mg/4 mL 200 mg/10 mL 400 mg/20 mL	Injection
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**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	<b>Simponi</b>	golimumab	50 mcg/0.5 mL 50 mcg/0.5 mL	Injection
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**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 over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

02417472	<b>Simponi IV</b>	golimumab	50 mg/4 mL	Injection
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### **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	<b>Cimzia</b>	certolizumab	200 mg/mL	Injection
02465574	<b>Cimzia</b>	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 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 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.*

02516098	<b>Ilumya</b>	tildrakizumab	100 mg/mL	Injection	SPG
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For treatment of adult patients with severe plaque psoriasis presently with one or more of the following:

- Psoriasis Area and the Severity Index (PASI)  $\geq$  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:

- $\geq$  50% reduction in the PASI score with  $\geq$  5 point improvement in the DLQI
- $\geq$  75 % reduction in the PASI score
- $\geq$  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.*

02320673 02320681	<b>Stelara</b>	ustekinumab	45 mg/0.5 mL 90 mg/mL	Injection	
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### 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)  $\geq$  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:

- $\geq$  50% reduction in the PASI score with  $\geq$  5 point improvement in the DLQI
- $\geq$  75 % reduction in the PASI score
- $\geq$  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	<b>Cosentyx</b>	secukinumab	150 mg/mL	Injection
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**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)  $\geq$  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:

- $\geq$  50% reduction in the PASI score with  $\geq$  5 point improvement in the DLQI
- $\geq$  75 % reduction in the PASI score
- $\geq$  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 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**

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	<b>Taltz</b>	ixekizumab	80 mg/mL 80 mg/mL	Autoinjector Pre-filled Syringe
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**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)  $\geq$  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	<b>Siliq</b>	brodalumab	210 mg/1.5 mL	Injection
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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*

02487454	<b>Skyrizi</b>	risankizumab	90 mg/mL	Injection
02519283 02519291	<b>Skyrizi</b>	risankizumab	150 mg/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	<b>Aubagio</b>	teriflunomide	14 mg	Tablet
02269201	<b>Avonex</b>	interferon beta 1-a	30 mcg/0.5 mL	Injection
02418320	<b>Lemtrada</b>	alemtuzumab	12 mg/1.2 mL	Solution for IV Infusion
02237319	<b>Rebif</b>	interferon beta 1-a	22 mcg/0.5 mL	Injection
02237320	<b>Rebif</b>	interferon beta 1-a	44 mcg/0.5 mL	Injection
02169649	<b>Betaseron</b>	interferon beta 1-b	0.3 mg	Injection
02245619	<b>Copaxone</b>	glatiramer acetate	20 mg/mL	Pre-Filled Syringe
02460661	<b>Glatect</b>	glatiramer acetate	20 mg	Pre-Filled Syringe
02365480	<b>Gilenya</b>	fingolimod	0.5 mg	Capsule
02469936	<b>Apo-Fingolimod</b>	fingolimod	0.5 mg	Capsule
02487772	<b>Jamp-Fingolimod</b>	fingolimod	0.5 mg	Capsule
02474743	<b>Mar-Fingolimod</b>	fingolimod	0.5 mg	Capsule
02469715	<b>Mylan-Fingolimod</b>	fingolimod	0.5 mg	Capsule
02469782	<b>pms-Fingolimod</b>	fingolimod	0.5 mg	Capsule
02482606	<b>Sandoz-Fingolimod</b>	fingolimod	0.5 mg	Capsule
02469618	<b>Taro-Fingolimod</b>	fingolimod	0.5 mg	Capsule
02469561	<b>Teva-Fingolimod</b>	fingolimod	0.5 mg	Capsule
02467224	<b>Ocrevus</b>	ocrelizumab	30 mg/mL	Injection
02444399 02444402	<b>Plegridy</b>	peginterferon beta-1a	125 mcg/0.5 mL 63 mcg.0.5 mL	Injection
02404508 02420201	<b>Tecfidera</b>	dimethyl fumarate	120 mg 240 mg	Capsule
02495341 02495368	<b>ACH-Dimethyl Fumarate</b>	dimethyl fumarate	120 mg 240 mg	Capsule
02505762 02505770	<b>Apo-Dimethyl Fumarate</b>	dimethyl fumarate	120 mg 240 mg	Capsule
02494809 02494817	<b>GLN-Dimethyl Fumarate</b>	dimethyl fumarate	120 mg 240 mg	Capsule
02516047 02516055	<b>Jamp Dimethyl Fumarate</b>	dimethyl fumarate	120 mg 240 mg	Capsule
02502690 02502704	<b>Mar-Dimethyl Fumarate</b>	dimethyl fumarate	120 mg 240 mg	Capsule
02497026 02497034	<b>pms-Dimethyl Fumarate</b>	dimethyl fumarate	120 mg 240 mg	Capsule

02513781 02513803	<b>Sandoz Dimethyl Fumarate</b>	dimethyl fumarate	120 mg 240 mg	Capsule
02286386	<b>Tysabri</b>	natalizumab	300 mg/15 mL	Injection

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

***Glatect will be a preferred glatiramer acetate option for all glatiramer acetate-naive 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 previously trialed and deemed unresponsive to therapy.***

02511355	<b>Kesimpta</b>	ofatumumab	20 mg/0.4 mL	Injection
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For the treatment of adult patients with an established diagnosis of relapsing-remitting multiple sclerosis (RRMS), when prescribed by a neurologist from the Manitoba Multiple Sclerosis (MS) Clinic.

02470179	<b>Mavenclad</b>	cladribine	10 mg	Tablet
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Specialists from the MS Clinic may apply for EDS. Please contact the EDS Program at MB Health for specific criteria.

02244550 02244552	<b>Pamidronate Disodium</b>	pamidronate disodium	3 mg/mL 9 mg/mL	Injection
02249685	<b>Pamidronate Disodium Omega</b>	pamidronat+A1698:C1721e disoc	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	<b>Advagraf</b>	tacrolimus	0.5 mg 1 mg 3 mg 5 mg	Capsule
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For the prophylaxis of organ rejection in patients receiving allogeneic liver or kidney transplants.

02485877 02485885 02485893	<b>Envarus PA</b>	tacrolimus	0.75 mg 1 mg 4 mg	Extended Release Tablet
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For the prophylaxis of organ rejection in patients receiving allogeneic liver or kidney transplants.

02243144 02175991 02175983	<b>Prograf</b>	tacrolimus	0.5 mg 1 mg 5 mg	Capsule
02176009	<b>Prograf</b>	tacrolimus	5 mg/mL	Injection
00960632	<b>Prograf</b>	tacrolimus	0.5 mg/ mL	Suspension

02416816 02416824 02416832	<b>Sandoz Tacrolimus</b>	tacrolimus	0.5 mg 1 mg 5 mg	Capsule
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(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.

02264560 02264579	<b>Myfortic</b>	mycophenolate sodium	180 mg 360 mg	Tablet
02372738 02372746	<b>Apo-Mycophenolic Acid</b>	mycophenolate sodium	180 mg 360 mg	Tablet
02511673 02511681	<b>Mar-Mycophenolic Acid</b>	mycophenolic sodium	180 mg 360 mg	Tablet

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

02248540	<b>Apo-Tryptophan</b>	l-tryptophan	500 mg	Capsule
02248538 02458721 02248539	<b>Apo-Tryptophan</b>	l-tryptophan	500 mg 750 mg 1 g	Tablet
02240334	<b>ratio-Tryptophan</b>	l-tryptophan	500 mg	Capsule
02240333 02237250	<b>ratio-Tryptophan</b>	l-tryptophan	500 mg 1 g	Tablet
00718149	<b>Tryptan</b>	l-tryptophan	500 mg	Capsule
02029456 00654531	<b>Tryptan</b>	l-tryptophan	500 mg 1 g	Tablet

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

02478862 02478870	<b>Accel-Leflunomide</b>	leflunomide	10 mg 20 mg	Tablet
02256495 02256509	<b>Apo-Leflunomide</b>	leflunomide	10 mg 20 mg	Tablet
02351668 02351676	<b>Leflunomide</b>	leflunomide	10 mg 20 mg	Tablet
02241888 02241889	<b>Arava</b>	leflunomide	10 mg 20 mg	Tablet
02261251 02261278	<b>Novo-Leflunomide</b>	leflunomide	10 mg 20 mg	Tablet
02283964 02283972	<b>Sandoz Leflunomide</b>	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	<b>Diane-35</b>	cyproterone acetate/ ethinyl estradiol	2 mg/0.035 mg	Tablet
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02290308	<b>Cyestra-35</b>	cyproterone acetate/ ethinyl estradiol	2 mg/0.035 mg	Tablet
02309556	<b>Novo- Cyproterone/Ethinyl Estradiol</b>	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).

01968017 02420104 02420112	<b>Neupogen</b>	filgrastim	300 mcg/mL 300 mcg/0.5 mL 480 mcg/0.8 mL	Injection
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For the use in patients with HIV infection for the prevention and treatment of neutropenia to maintain a normal absolute neutrophil count (ANC).

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

02441489 02454548	<b>Grastofil</b>	filgrastim	300 mcg/0.5 mL 480 mcg/0.8 mL	Injection
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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 a preferred filgrastim option for all filgrastim-naive patients. Preferred means the first filgrastim product to be considered for reimbursement for filgrastim-naive patients.***

02485575 02485583 02485591 02485656	<b>Nivestym</b>	filgrastim	300 mcg/0.5 mL 480 mcg/0.8 mL 300 mcg/mL 480 mcg/1.6 mL	Injection
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For the use in patients with HIV infection for the prevention and treatment of neutropenia to maintain a normal absolute neutrophil count (ANC).

***Nivestym will be a preferred filgrastim option for all filgrastim-naive patients. Preferred means the first filgrastim product to be considered for reimbursement for filgrastim-naive patients.***

02387174	<b>Dificid</b>	fidaxomicin	200 mg	Tablet
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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	<b>Esbriet</b>	pirfenidone	267 mg	Capsule
02464489 02464500	<b>Esbriet</b>	pirfenidone	267 mg 801 mg	Tablet
02509938	<b>Jamp Pirfenidone</b>	pirfenidone	267 mg	Capsules
02514702 02514710	<b>Jamp Pirfenidone</b>	pirfenidone	267 mg 801 mg	Tablets
02488833	<b>Sandoz Pirfenidone</b>	pirfenidone	267 mg	Capsules
02488507 02488515	<b>Sandoz Pirfenidone</b>	pirfenidone	267 mg 801 mg	Tablets

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.

02443066 02443074	<b>Ofev</b>	nintedanib	100 mg 150 mg	Capsule
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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.

### **Chronic fibrosing interstitial lung diseases**

#### Initiation criteria:

- The patient has a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype confirmed by a specialist in interstitial lung diseases.
- The patient has a forced vital capacity greater than or equal to 45% of predicted.

#### Renewal criteria:

- The patient must not experience a more severe progression of disease, defined as an absolute decline in percent predicted forced vital capacity of 10% or greater over the preceding year of treatment with nintedanib.
- The patient's clinical status should be evaluated every 12 months.

#### Prescribing conditions:

- The patient's condition has been assessed by a specialist with experience in the diagnosis and management of interstitial lung diseases.
- Concurrent treatment of nintedanib with pirfenidone should not be reimbursed.

02470632	<b>Trispan</b>	triamcinolone hexacetonide	20 mg/mL	Injection
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For the management of pediatric chronic inflammatory arthropathies.

02455897	<b>Apo-Cabergoline</b>	cabergoline	0.5 mg	Tablet
02242471	<b>Dostinex</b>	cabergoline	0.5 mg	Tablet

For treatment of:

- a) Hyperprolactinemic disorders in patients unresponsive to bromocriptine.
- b) Hyperprolactinemic disorders in patients intolerant to bromocriptine.

02473232 02496135	<b>Fasenra</b>	benralizumab	30 mg/mL	Injection
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As add-on maintenance treatment for adult patients with severe eosinophilic asthma, if the following criteria are met:

**Initiation Criteria**

1. Patient must have a documented diagnosis of asthma.
2. Patient is inadequately controlled with high-dose inhaled corticosteroids, defined as greater or equal to 500 mcg of fluticasone propionate or equivalent daily, and one or more additional asthma controller(s) (e.g., long-acting beta agonists).
3. Patient has one of the following:
  - 3.1. blood eosinophil count of  $\geq 300$  cells/ $\mu$ L within the past 12 months AND has experienced two or more clinically significant asthma exacerbations in the past 12 months, or
  - 3.2. blood eosinophil count of  $\geq 150$  cells/ $\mu$ L AND is receiving maintenance treatment with oral corticosteroids (OCS).

**Administration Criteria**

1. Benralizumab should not be used in combination with other biologics used to treat asthma.
2. A baseline assessment of asthma symptom control using a validated asthma control questionnaire must be completed prior to initiation of benralizumab treatment.
3. Patients should be managed by a physician with expertise in treating asthma.

**Renewal Criteria**

1. The effects of treatment should be assessed every 12 months to determine whether reimbursement should continue.
2. Reimbursement of treatment should be discontinued if:
  - 2.1. the 12 month asthma control questionnaire score has not improved from baseline, when baseline represents the initiation of treatment, or
  - 2.2. the asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or
  - 2.3. the number of clinically significant exacerbations has increased within the previous 12 months, or
  - 2.4. in patients on maintenance treatment with OCS, there has been no decrease in the OCS dose in the first 12 months of treatment, or
  - 2.5. in patients on maintenance treatment with OCS, the reduction in the dose of OCS achieved after the first 12 months of treatment is not maintained subsequently.