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.

CARDIOVASCULAR

02273233 02273284 02273241 02273292 02273268 02273306 02273276 02273314	**Caduet**	amlodipine/atorvastatin	5/10 mg 10/10 mg 5/20 mg 10/20 mg 5/40 mg 10/40 mg 5/80 mg 10/80 mg	Tablet
02411253 02411261 02411288 02411296 02411318 02411326 02411334 02411342	**Apo-Amlodipine/ Atorvastatin**	amlodipine/atorvastatin	5/10 mg 5/20 mg 5/40 mg 5/80 mg 10/10 mg 10/20 mg 10/40 mg 10/80 mg	Tablet
02362759 02362767 02362775 02362783 02362791 02362805 02362813 02362821	**Mylan-Amlodipine/ Atorvastatin**	amlodipine/atorvastatin	5/10 mg 5/20 mg 5/40 mg 5/80 mg 10/10 mg 10/20 mg 10/40 mg 10/80 mg	Tablet

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.

02495244	**Vascepa**	icosapent ethyl	1 G	Capsule

To reduce the risk of cardiovascular events in statin-treated patients with elevated triglycerides, who meet all of the following criteria:

- Aged 45 years or older; AND
- Established cardiovascular disease (CVD) [1] (secondary prevention); AND
- Baseline fasting triglyceride level greater than or equal to 1.7 mmol/L and lower then 5.6 mmol/L, measured within the preceding 3 months before starting treatment with icosapent ethyl, AND
- Baseline low-density lipoprotein cholesterol (LDL-C) level greater than 1.0mmol/L and lower than 2.6 mmol/L; AND
- Receiving a maximally tolerated statin dose for a minimum of 4 weeks, targeted to achieve an LDL-C lower than 2.0 mmol/L.

[1] Established CVD is defined as: history of coronary artery disease (eg. Myocardial infarction, angina, coronary procedure, abdominal aortic aneurysm), cerebrovascular disease (eg. stroke, transient ischemic attack, carotid obstruction), or peripheral artery disease.

Note: Approval will be for a maximum of 4g daily.

02531917 02531925	**Kerendia**	finerenone	10mg 20mg	Tablet

For use as an adjunct to standard of care[1] therapy to reduce the risk of end-stage kidney disease and a sustained decrease in estimated glomerular filtration rate (eGFR), cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure, in adult patients with BOTH chronic kidney disease AND type 2 diabetes who meet all of the following criteria:

- eGFR level greater than or equal to 25 mL/min/1.73 m2; AND
- Urine albumin-creatinine ratio (UACR) greater than or equal to 30 mg/g (or 3 mg/ mmol); AND
- Patient does not have New York Heart Association (NYHA) class II to IV heart failure; AND
- Patient is not using finerenone in combination with another mineralocorticoid receptor antagonist.

[1]Standard of care is defined as maximally tolerated doses of an angiotensin- converting enzyme (ACE) inhibitor or angiotensin-receptor blocker (ARB) therapy in combination with a sodium-glucose cotransporter 2 (SGLT2) inhibitor, unless SGLT2 inhibitors are contraindicated or not tolerated.

Treatment with finerenone should be discontinued if:

- eGFR level is less than 15 mL/min/1.73 m^2; OR
- UACR has increased from baseline

Finerenone must be prescribed in consultation with a nephrologist, or by a prescriber with experience in the diagnosis and management of patients with CKD and T2D.

AUTONOMIC DRUGS

02242115 02242116 02242117 02242118	**Exelon**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02245240	**Exelon**	rivastigmine	2 mg/mL	Oral Liquid
02336715 02336723 02336731 02336758	**Apo-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02485362 02485370 02485389 02485397	**Jamp-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02401614 02401622 02401630 02401649	**Med-Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule
02324563 02324571 02324598 02324601	**Sandoz Rivastigmine**	rivastigmine	1.5 mg 3 mg 4.5 mg 6 mg	Capsule

Confirmed diagnosis of Alzheimer's Disease with DSMIV criteria with:

(a) Memory impairment (impaired ability to learn new information or to recall previously learned information); plus

(b) at least one of the following:

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

The above deficits must have:

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

02518058	**Breztri Aerosphere**	budesonide/glycopyrronium/ fomoterol	160/7.2/5.0 mcg	Metered Dose Inhaler

For the long-term maintenance treatment of chronic obstructive pulmonary disease (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

02501244	**Enerzair Breezhaler**	glycopyrronium/indacaterol/ mometasone furoate	50/150/160 mcg	Capsule

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	**Trelegy Ellipta**	fluticasone furoate/ umeclidinium/vilanterol	100 mcg/ 62.5 mcg/25 mg	Powder for Inhalation

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

02532247 02532255 02532263 02533271 02532298	**Elonox**	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	Injection
02532301 02532328	**Elonox HP**	enoxaparin sodium	120 mg/0.8 mL 150 mg/mL	Injection
02507501 02507528 02507536 02507544 02507552	**Inclunox** *(biosimilar)*	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	Injection
02507560 02507579	**Inclunox-HP** *(biosimilar)*	enoxaparin sodium	120 mg/0.8 mL 150 mg/1 mL	Injection
02506440 02506459 02506467 02506475 02506483 02506491	**Noromby** *(biosimilar)*	enoxaparin sodium	20 mg/0.2 mL 30 mg/0.3 mL 40 mg/0.4 mL 60 mg/0.6 mL 80 mg/0.8 mL 100 mg/mL	Injection
02506505 02506513	**Noromby HP** *(biosimilar)*	enoxaparin sodium	120 mg/0.8 mL 150 mg/mL	Injection
02509075 02509083 02509091 02509105 02509113 02509121	**Redesca** *(biosimilar)*	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	**Redesca HP** *(biosimilar)*	enoxaparin sodium	120 mg/0.8 mL 150 mg/mL	Injection

1. For prophylaxis of thromboembolic disorders (DVT) in patients undergoing orthopedic surgery of the hip or knee.

2. For treatment of deep venous thrombosis (DVT).
3. Peri-operatively if a high risk of thromboembolism exists (i.e., requiring anticoagulation where warfarin is withheld).
4. For treatment of recurrent DVT or pulmonary embolism occurring on therapeutic warfarin.
5. For antithrombotic therapy in pediatrics.
6. For antithrombotic therapy during pregnancy (extend coverage for 2 weeks past due date).
7. For prophylaxis of thromboembolic disorders in spinal cord injury for a maximum of 8 to 12 weeks.
8. For the prevention of venous thromboembolism in patients undergoing pelvic or abdominal surgery for cancer (4 week duration).
9. For the prevention of venous thromboembolism in patients undergoing pelvic or abdominal surgery for inflammatory bowel disease (4 week duration).

02132621 02430789 02132648 02231171 02352680 02352648 02352672 02352656 02352664	**Fragmin**	dalteparin	2500 IU/0.2 mL 3500 IU/0.28 mL 5000 IU/0.2 mL 25000 IU/mL 18000IU/0.72 mL 7500 IU/0.3 mL 15000 IU/0.6 mL 10000 IU/0.4 mL 12500 IU/0.5 mL	Injection
02236913 02240114	**Fraxiparine**	nadroparin	9500 IU/mL 19000 IU/mL	Injection
02229755 02167840 02231478 02229515 02358182 02358158 02358166 02358174 02429462 02429470 02429489	**Innohep**	tinzaparin	2500 IU/0.25 mL 10000 IU/mL 10000 IU/0.5 mL 20000 IU/mL 18000 IU/0.9 mL 3500 IU/0.35 mL 4500 IU/0.45 mL 14000 IU/0.7 mL 8,000/0.4 mL 12,000/0.6 mL 16,000/0.8 mL	Injection

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

02458640 02458659 02458667	**Lixiana**	edoxaban	15 mg 30 mg 60 mg	Tablet
02312441 02358808	**Pradaxa**	dabigatran	110 mg 150 mg	Capsule
02468905 02468913	**Apo-Dabigatran**	dabigatran	110 mg 150 mg	Capsule

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).

02458640 02458659 02458667	**Lixiana**	edoxaban	15 mg 30 mg 60 mg	Tablet

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

IRON PREPARATIONS

02477777	**Monoferric**	iron	100 mg/mL	Injection

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	**Venofer**	iron sucrose	20 mg/mL	Injectable Solution
02502917	**pms-Iron Sucrose**	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	**Alertec**	modafinil	100 mg	Tablet
02285398	**Apo-Modafinil**	modafinil	100 mg	Tablet
02430487	**Auro-Modafinil**	modafinil	100 mg	Tablet
02503727	**Jamp Modafinil**	modafinil	100 mg	Tablet

02432560	**Mar-Modafinil**	modafinil	100 mg	Tablet
02530244	**Modafinil**	modafinil	100 mg	Tablet
02420260	**Teva-Modafinil**	modafinil	100 mg	Tablet

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

02262827 02262835	**Strattera**	atomoxetine	25 mg 40 mg	Capsule
02318024 02318032 02318040 02318059 02318067 02318075	**Apo-Atomoxetine**	atomoxetine	10 mg 18 mg 25 mg 40 mg 60 mg 80 mg	Capsule
02445883 02445905 02445913 02445948 02445956	**Atomoxetine**	atomoxetine	10 mg 18 mg 25 mg 40 mg 60 mg	Capsule
02506807 02506815 02506823 02506831 02506858	**Jamp Atomoxetine**	atomoxetine	10 mg 18 mg 25 mg 40 mg 60 mg	Capsule
02386410 02386429 02386437 02386445 02386453 02386461 02386488	**Sandoz Atomoxetine**	atomoxetine	10 mg 18 mg 25 mg 40 mg 60 mg 80 mg 100 mg	Capsule
02314541 02314568 02314576 02314584 02314592 02362511	**Teva-Atomoxetine**	atomoxetine	10 mg 18 mg 25 mg 40 mg 60 mg 80 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

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

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

02426862 02426870 02426889 02426897	**Aptiom**	eslicarbazepine	200 mg 400 mg 600 mg 800 mg	Tablet
02452936 02452944 02452952 02452960 02452979	**Brivlera**	brivaracetam	10 mg 25 mg 50 mg 75 mg 100 mg	Tablet
02538679 02538687 02538695 02538709 02538717	**Apo-Brivaracetam**	brivaracetam	10 mg 25 mg 50 mg 75 mg 100 mg	Tablet
02539292 02539306	**Auro-Brivaracetam**	brivaracetam	50 mg 100 mg	Tablet
02357615 02357623 02357631 02357658	**Vimpat**	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02475332 02475340 02475359 02475367	**Auro-Lacosamide**	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02489287 02489295 02489309 02489317	**ACH-Lacosamide**	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet

02488388 02488396 02488418 02488426	**Jamp-Lacosamide**	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02512874 02512882 02512890 02512904	**Lacosamide (Sanis)**	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02487802 02487810 02487829 02487837	**Mar-Lacosamide**	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02490544 02490552 02490560 02490579	**Mint-Lacosamide**	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02499568 02499576 02499584 02499592	**NRA-Lacosamide**	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02478196 02478218 02478226 02478234	**Pharma-Lacosamide**	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02474670 02474689 02474697 02474700	**Sandoz Lacosamide**	lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet
02472902 02472910 02472929 02472937	**Teva-Lacosamide**	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 02404524 02404532 02404540 02404559 02404567	**Fycompa**	perampanel	2 mg 4 mg 6 mg 8 mg 10 mg 12 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

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	**Ajovy**	fremanezumab	225 mg/1.5 mL	Injection

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[1], intolerance, or contraindication to at least two oral prophylactic migraine medications[2] 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.

[1] 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.

[2] *Oral prophylactic medication alternatives include:*
- *beta blockers*
- *tricyclic antidepressants*
- *verapamil or flunarizine*
- *sodium valproate or divalproex sodium*
- *topiramate*
- *gabapentin*

02491087 02491060	**Emgality**	galcanezumab	120 mg/mL	Injection

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.

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[2] *Oral prophylactic medication alternatives include:*
- *beta blockers*
- *tricyclic antidepressants*
- *verapamil or flunarizine*
- *sodium valproate or divalproex sodium*
- *topiramate*
- *gabapentin*

02510839	**Vyepti**	eptinezumab	100 mg/ mL	Solution
02542269	**Vyepti**	eptinezumab	300 mg/3 mL	Solution

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 least 8 days per month are with migraine.

Initiation criteria:

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• 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.

[1]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.

[2]Oral prophylactic medication alternatives include:
• beta blockers
• tricyclic antidepressants
• verapamil or flunarizine
• sodium valproate or divalproex sodium
• topiramate
• gabapentin

02533979 02533987 02533995	**Qulipta**	atogepant	10 mg 30 mg 60 mg	Tablet

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[1], intolerance, or contraindication to at at least two oral prophylactic migraine medications[2] 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.

[1]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.

[2]Oral prophylactic medication alternatives include:
• beta blockers
• tricyclic antidepressants
• verapamil or flunarizine
• sodium valproate or divalproex sodium
• topiramate
• gabapentin

Combined use with other calcitonin gene-related peptide (CGRP) inhibitors will not be reimbursed.

Opiate Agonists				
02230302 02163748 02163780 02163799	**Codeine Contin**	codeine	50 mg 100 mg 150 mg 200 mg	Sustained Release Tablet

For the treatment of:
(a) **Palliative and chronic pain** in patients where hepatotoxicity is a concern due to high doses of acetaminophen (e.g. taking over 12 tablets of acetaminophen compound with codeine 30 mg per day).
(b) **Codeine addiction** using tapering doses.

02231934 02240131 02240132	**Oxy-IR**	oxycodone HCl	5 mg 10 mg 20 mg	Tablet
02319977 02319985 02319993	**pms-Oxycodone**	oxycondone HCl	5 mg 10 mg 20 mg	Tablet
00789739 00443948 02262983	**Supeudol**	oxycodone HCl	5 mg 10 mg 20 mg	Tablet

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

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

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

Selective Serotonin and Norepinephrine Reuptake Inhibitors

02420864 02420872	**Abilify Maintena**	aripiprazole	300 mg/vL 400 mg/vL	Injection
02354217 02354225 02354233 02354241	**Invega Sustenna**	paliperidone	50 mg/0.5 mL 75 mg/0.75 mL 100 mg/mL 150 mg/1.5 mL	Injection
02455943 02455986 02455994 02456001	**Invega Trinza**	paliperidone	175 mg/0.875 mL 263 mg/1.315 mL 350 mg/1.75 mL 525 mg/2.625 mL	Injection
02298465 02255707 02255723 02255758	**Risperdal Consta**	risperidone	12.5mg 25 mg 37.5 mg 50 mg	Injection

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

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

ELECTROLYTIC, CALORIC AND WATER BALANCE

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

Portal systemic encephalopathy.

02410702	**Zaxine**	rifaximin	550 mg	Tablet

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

EYE, EAR, NOSE AND THROAT PREPARATIONS

02248151	**Alphagan P**	brimonidine tartrate	0.15%	Ophthalmic Solution
02301334	**Apo-Brimonidine P**	brimonidine tartrate	0.15%	Ophthalmic Solution

Intolerance to brimonidine 0.2%.

02484137	**Verkazia**	cyclosporine	0.1%	Emulsion

For the treatment of severe vernal keratoconjunctivitis (VKC) in patients who meet ALL of the following criteria:

- Patient is between 4 and 18 years of age inclusive; AND
- Diagnosis of severe VKC defined as either:
  - o Grade 3 (severe) or 4 (very severe) on the Bonini scale, OR
  - o Grade 4 (marked) or 5 (severe) on the modified Oxford scale; AND
- Documentation of the baseline severity of signs and symptoms of VKC prior to treatment initiation is provided; AND
- Patient is under the care of a specialist physician with experience in the diagnosis and management of VKC.

Note: Patients previously treated with cyclosporine 0.1% but who discontinued treatment upon resolution of VKC signs and symptoms are eligible to reinitiate treatment if signs and symptoms of severe VKC recur and they meet the initiation criteria.

Initial approval period: 6 months

Discontinuation Criteria:

- Treatment should be discontinued if no improvement in signs and symptoms of VKC is observed; OR
- Treatment should be discontinued once signs and symptoms of VKC have resolved.

GASTROINTESTINAL DRUGS

02470780	**Apo-Lansoprazole-Amoxicillin-Clarithromycin**	amoxicillin/clarithromycin/ lansoprazole	500 mg 500 mg 30 mg	Tablet

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

02256452	**Jamp-Loperamide**	loperamide	2 mg	Tablet
02132591	**Novo-Loperamide**	loperamide	2 mg	Tablet
02228351	**pms-Loperamide**	loperamide	2 mg	Tablet

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

HORMONES AND SYNTHETIC SUBSTITUTES

02229293	**Entocort**	budesonide	3 mg	Capsule

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

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

For use in patients who are not optimally controlled on maximal doses of metformin and

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

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

02269589 02269597 02269619	**Sandoz Glimepiride**	glimepiride	1 mg 2 mg 4 mg	Tablet

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

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

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

02425483 02425491	**Invokana**	canagliflozin	100 mg 300 mg	Tablet
02388839 02388847 02303922	**Januvia**	sitagliptin	25 mg 50 mg 100 mg	Tablet
02512475 02512483 02512491	**ACH-Sitagliptin**	sitagliptin	25 mg 50 mg 100 mg	Tablet
02508656 02508664 02508672	**Apo-Sitagliptin**	sitagliptin	25 mg 50 mg 100 mg	Tablet
02529866 02529874 02529882	**Auro-Sitagliptin**	sitagliptin	25 mg 50 mg 100 mg	Tablet

02534134 02534142 02534150	**Jamp Sitagliptin**	sitagliptin	25 mg 50 mg 100 mg	Tablet
02503840 02503859 02503867	**pms-Sitagliptin**	sitagliptin	25 mg 50 mg 100 mg	Tablet
02504049 02504057 02504065	**Sandoz Sitagliptin**	sitagliptin	25 mg 50 mg 100 mg	Tablet
02548550 02548569 02548577	**Sitagliptin**	sitagliptin	25 mg 50 mg 100 mg	Tablet
02529033 02529041 02529068	**Sitagliptin**	sitagliptin	25 mg 50 mg 100 mg	Tablet
02531631 02531658 02531666	**Taro-Sitagliptin Fumarate**	sitagliptin	25 mg 50 mg 100 mg	Tablet
02522705 02522713 02522721	**Teva-Sitagliptin Malate**	sitagliptin	25 mg 50 mg 100 mg	Tablet
02443937 02443945	**Jardiance**	empagliflozin	10 mg 25 mg	Tablet
02375842 02333554	**Onglyza**	saxagliptin	2.5 mg 5 mg	Tablet
02507471 02507498	**Apo-Saxagliptin**	saxagliptin	2.5 mg 5 mg	Tablet
02468603 02468611	**Sandoz Saxagliptin**	saxagliptin	2.5 mg 5 mg	Tablet
02370921	**Trajenta**	linagliptin	5 mg	Tablet

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

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

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

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

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

- History of myocardial infarction (MI).

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

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

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

NOTE: Patients must meet EDS criteria for empagliflozin.

02333856 02333864 02333872	**Janumet**	sitagliptin/metformin	50/500 mg 50/850 mg 50/1000 mg	Tablet
02509415 02509423 02509431	**Apo-Sitagliptin Malate/ Metformin**	sitagliptin/metformin	50/500 mg 50/850 mg 50/1000 mg	Tablet
02503956 02503964 02503972	**Sandoz Sitagliptin-Meformin**	sitagliptin/metformin	50/500 mg 50/850 mg 50/1000 mg	Tablet
02416794	**Janumet XR**	sitagliptin/metformin	50/1000 mg	Tablet
02506270 02506289 02506297	**Apo-Sitagliptin/Metformin XR**	sitagliptin/metformin	50/500 mg 50/1000 mg 100/1000 mg	Tablet
02529106 02529114 02529122	**Sandoz Sitagliptin-Meformin XR**	sitagliptin/metformin	50/500 mg 50/1000 mg 100/1000 mg	Tablet
02403250 02403269 02403277	**Jentadueto**	linagliptin/metformin	2.5/500 mg 2.5/850 mg 2.5/1000 mg	Tablet
02389169 02389177 02389185	**Komboglyze**	saxagliptin/metformin	2.5/500 mg 2.5/850 mg 2.5/1000 mg	Tablet

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.

02471469 02471477 02540258	**Ozempic**	semaglutide	1.34 mg/mL 1.34 mg/mL 0.68mg/mL	Injection

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.

02478293	**Soliqua**	insulin glargine/lixisenatide	100 U/33 mcg	Injection

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.

02251930	**Lantus**	insulin glargine	100 U/mL	Injection Cartridge

For pediatric patients who require a half-unit pen device to administer insulin glargine.

02245397	**NovoRapid**	insulin aspart	100 U/mL	Injection Vial

For patients requiring an insulin aspart vial for use with an insulin pump.

MISCELLANEOUS SKIN AND MUCOUS MEMBRANE AGENTS

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

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

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

02528363 02528371 02528398	**Cibinqo**	abrocitinib	50 mg 100 mg 200 mg	Tablet

For the treatment of refractory moderate to severe[1] atopic dermatitis (AD), in patients aged 12 years and older, only if the following criteria are met:

Initiation criteria:

- Patient has had an adequate trial[2] (with a documented refractory disease), or was intoleratnt (with documented intolerance), or is ineligible for each of the following therapies:
  - o maximally tolerated medical topical therapies for AD combined with phototherapy (where available); AND
  - o maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine).
- The physician must provide the Eczema Area and Severity Index (EASI) score at the time of initial request for reimbursement.

Initial approval: 6 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) 6 months after treatment initiation.
• The physician must provide proof of maintenance of EASI-75 response from baseline for subsequent authorizations.

Renewal approval: 1 year

Request for coverage must be made by, or in consultation with, a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD.

Abrocitinib should not be used in combination with phototherapy, any immunomodulatory agents (including biologics) or other Janus kinase [JAK] inhibitor treatment for moderate to severe AD.

[1]Moderate to severe atopic dermatitis is defined as an EASI score of 16 points or higher.
[2] Adequate trials are defined as:
- Phototherapy – 3 times a week for 12 weeks.
- Methotrexate – 10 to 20mg per week for 12 weeks.
- Cyclosporine – 2.5 to 5mg/kg/day for 12 weeks.
- Mycophenolate mofetil – 1g twice daily for 12 weeks.
- Azathioprine – 1.5 to 2.5mg/kg/day for 12 weeks.

02470365 02492504 02510049 02524252	**Dupixent**	dupilumab	150 mg/mL 200 mg/1.14 mL 150 mg/mL 200 mg/1.14 mL	Injection

For the treatment of moderate-to-severe[1] atopic dermatitis (AD) in patients aged 12 years and older, whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable, only if the following criteria are met:

Initiation Criteria

• Patient has had an adequate trial[2](with a documented refractory disease), or was intolerant (with documented intolerance), or is ineligible for each of the following therapies:
  o maximally tolerated medical topical therapies for AD combined with phototherapy (where available); AND
  o maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine).
• The physician must provide the Eczema Area and Severity Index (EASI) score at the time of initial request for reimbursement.

Initial approval: 6 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.

Request for coverage must be made by, or in consultation with, a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate-to-severe AD.

Dupilumab should not be used in combination with phototherapy, any immunomodulatory drugs (including biologics or a Janus kinase [JAK] inhibitor treatment) for moderate-to-severe AD.

[1] Moderate-to-severe atopic dermatitis is defined as an EASI score of 16 points or higher

[2] Adequate trials are defined as:

- Phototherapy – 3 times a week for 12 weeks.
- Methotrexate – 10 to 20mg per week for 12 weeks.
- Cyclosporine – 2.5 to 5mg/kg/day for 12 weeks.
- Mycophenolate mofetil – 1g twice daily for 12 weeks.
- Azathioprine – 1.5 to 2.5mg/kg/day for 12 weeks.

02495155 02520893	**Rinvoq**	upadacitinib	15 mg 30 mg	Tablet

Atopic Dermatitis

For the treatment of refractory moderate to severe[1] atopic dermatitis (AD), in patients aged 12 years and older, only if the following criteria are met:

Initiation Criteria:

- Patient has had an adequate trial[2] (with a documented refractory disease), or was intolerant (with documented intolerance), or is ineligible for each of the following therapies:
  - o maximally tolerated medical topical therapies for AD combined with phototherapy (where available); AND
  - o maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine).
- The physician must provide the Eczema Area and Severity Index (EASI) score at the time of initial request for reimbursement.

Initial approval: 6 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) 6 months after treatment initiation.
- The physician must provide proof of maintenance of EASI-75 response from baseline for subsequent authorizations.

Renewal approval: 1 year

Request for coverage must be made by, or in consultation with, a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD.

Upadacitinib should not be used in combination with phototherapy, any immunomodulatory agents (including biologics) or other Janus kinase [JAK] inhibitor treatment for moderate to severe AD.

[1] Moderate to severe atopic dermatitis is defined as an EASI score of 16 points or higher.

[2] Adequate trials are defined as:

- Phototherapy – 3 times a week for 12 weeks.
- Methotrexate – 10 to 20mg per week for 12 weeks.

• Cyclosporine – 2.5 to 5mg/kg/day for 12 weeks.
• Mycophenolate mofetil – 1g twice daily for 12 weeks.
• Azathioprine – 1.5 to 2.5mg/kg/day for 12 weeks.

SMOOTH MUSCLE RELAXANTS

02275066	**Trosec**	trospium	20 mg	Tablet
02488353	**Mar-Trospium**	trospium	20 mg	Tablet
02506661	**JampTrospium**	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

02542420	**Amvuttra**	vutrisiran	25 mg/0.5 mL	Pre-Filled Syringe
02489252	**Onpattro**	patisiran	2 mg/mL	Solution
02481383	**Tegsedi**	inotersen	284 mg/1.5 mL	Injection

Initiation Criteria:
For the treatment of polyneuropathy in patients with hereditary transthyretin-mediated amyloidosis (hATTR), meeting all the following criteria:

1. Age 18 years of age or older; AND
2. Has a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis; AND
3. Symptomatic with polyneuropathy disability (PND) stage I to less than or equal to IIIB or with familial amyloidotic polyneuropathy (FAP) stage I or II; AND
4. Under the care of a specialist with experience in the diagnosis and management of hATTR.

Exclusion Criteria:
- Pre-symptomatic patients
- Patients diagnosed with severe heart failure symptoms (defined as New York Heart Association class III or IV)
- Patients who are recipients of a liver transplant
- Patients who will be using vutrisiran in combination with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR.

Discontinuation Criteria:
Treatment with vutrisiran will be discontinued for patients who are:
- Permanently bedridden and dependent on assistance for basic activities of daily living, or
- Receiving end-of-life/palliative care where survival of less than one year is expected.

Renewal Criteria:
Renewal of funding will be considered if patients do not meet the discontinuation criteria.

Patients should be assessed after 9 months of treatment and then every six months thereafter.

Duration of Approval of initiation requests: 10 months
Duration of Approval of first renewal: 6 months
Duration of Approval of 2nd and subsequent renewals: 1 year

Notes to Prescribers:
• Laboratory documentation for the genetic mutation for hATTR must be included with the application.

• Signs and symptoms of polyneuropathy should be listed.
• In your application, please list all drugs that the patient is using including whether they are using any of the following: diflunisal, inotersen, tafamidis, patisiran.
• Confirmation that the patient does not meet each of the listed exclusions must be provided on the request.

Definitions:
Familial Amyloid Polyneuropathy (FAP) stage: Clinical staging system for the neuropathy symptoms of hATTR (formerly termed familial amyloid neuropathy).
• FAP Stage 1: Walking without assistance, mild neuropathy (sensory, autonomic, and motor) in lower limbs
• FAP Stage 2: Walking with assistance, moderate impairment in lower limbs, trunk, and upper limbs
• FAP Stage 3: wheelchair or bed-ridden, severe neuropathy

Polyneuropathy disability score (PND): A five-stage measure of neuropathy impairment ranging from 0 (no impairment) to 4 (confined to a wheelchair or bedridden).
• Stage 0: no impairment
• Stage I: sensory disturbances but preserved walking capability
• Stage II: impaired walking capability but ability to walk without a stick or crutches
• Stage IIIA: walking only with the help of one stick or crutch
• Stage IIIB: walking with the help of two sticks or crutches
• Stage IV: confined to a wheelchair or bedridden

02298384	**Teva-Risedronate**	risedronate	30 mg	Tablet

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

02489597	**Evenity**	romosozumab	105 mg/1.17 mL	Pre-filled syringe

For the treatment of osteoporosis in postmenopausal women only if the following criteria are met:
• History of osteoporotic fracture; AND
• High risk for future fracture, defined as a 10-year fracture risk > 20% as defined by the Fracture Risk Assessment (FRAX) tool; AND
• Treatment naive to osteoporosis medications, except calcium and/or vitamin D.

Maximum duration of reimbursement is 12 months.

Note: Romosozumab will not be reimbursed if prescribed concurrently with other osteoporosis medications, except calcium and/or vitamin D.

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

To increase bone mass in men or postmenopausal women with osteoporosis who are at a high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:
High fracture risk defined as either:
- moderate 10-year fracture risk (10% to 20%) as defined by either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC} tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture;
OR
- high 10-year fracture risk (≥ 20%) as defined by either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC} tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool.
AND
Contraindication to oral bisphosphonates.

Notes:

• Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year.
• Contraindication to oral bisphosphonates will be considered. Contraindications include renal impairment, hypersensitivity, and abnormalities of the esophagus (e.g. esophageal stricture or achalasia).

Jubbonti will be the preferred denosumab option for all denosumab-naïve patients prescribed a denosumab product for osteoporosis. Preferred means the first denosumab product to be considered for reimbursement for denosumab-naive patients. Patients will not be permitted to switch from Prolia or Jubbonti to another denosumab product or vice versa, if previously trialed and deemed unresponsive to denosumab.

02545411	**Jubbonti** *(biosimilar)*	denosumab	60mg/mL	Injection

To increase bone mass in men or postmenopausal women with osteoporosis who are at a high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:

• High fracture risk defined as either:
  o 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
  o high 10-year fracture risk (≥ 20%) as defined by either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool.

AND

• Contraindication to oral bisphosphonates.

Notes:

• Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year.
• Contraindication to oral bisphosphonates will be considered. Contraindications include renal impairment, hypersensitivity, and abnormalities of the esophagus (e.g. esophageal stricture or achalasia).

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

1. Paget's disease.
2. a) For female patients with post-menopausal osteoporosis (PMO) at high risk for fracture and satisfy at least two of the following three criteria:
(i) Age > 75 years;

(ii) A prior fragility fracture;
(iii) A bone mineral density (BMD) T-score ≤ -2.5; OR
b) Female patients with PMO with a serious intolerance to oral bisphosphonates or for whom oral bisphosphonates are contraindicated.

02368153	**Xgeva**	denosumab	120 mg	Injection

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

2545764	**Wyost**	denosumab	120 mg/1.7 mL	Injection

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

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

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

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

02436841	**Entyvio**	vedolizumab	300 mg/vL	Injection
02497875 02497867	**Entyvio SC**	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 responsive, 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	**Orencia**	abatacept	125 mg/mL 250 mg/vial	Injection

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

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

02496933	**Avsola**	infliximab	100 mg/vial	Powder for Solution
02523191	**Ixifi**	infliximab	100 mg/vial	Powder for Solution
02419475	**Inflectra** **Remdantry**	infliximab	100 mg/vL	Injection
02470373	**Renflexis**	infliximab	100 mg	Injection

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.

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.

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

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 percent reduction in the PASI score with ≥ 5 point improvement in the DLQI
• ≥ 75 percent reduction in the PASI score
• ≥ 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.

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.

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.

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.

02511576	**Remsima SC**	infliximab	120 mg/mL	Pre-filled Syringe
02511584	**Remsima SC**	infliximab	120 mg/mL	Pre-filled Pen

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

Patient must have completed an induction regimen with intravenous infliximab, or be stabilized on intravenous infliximab in the maintenance setting, to continue to maintenance therapy with subcutaneous infliximab.

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

Ulcerative Colitis
For the treatment of adult 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.
Patient must have completed an induction regimen with intravenous infliximab, or be stabilized on intravenous infliximab in the maintenance setting, to continue to maintenance therapy with subcutaneous infliximab.

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

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.

02455323 02455331	**Brenzys**	etanercept	50 mg/mL	Injection
02462869 02462877 02462850	**Erelzi**	etanercept	50 mg/mL 25mg/0.5mL 50mg/mL	Injection
2530295	**Rymti**	etanercept	50 mg/mL	Pre-filled Syringe
2530309	**Rymti**	etanercept	50 mg/mL	Pre-filled Auto-Injector

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.

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.

Plaque 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) ≥ 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.

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.

02511061	**Abrilada**	adalimumab	20 mg/0.4 mL	Injection
02511053 02511045	**Abrilada**	adalimumab	40 mg/0.8 mL	Injection

02459310 02459299 02459302	**Amgevita**	adalimumab	50 mg/mL	Injection
02473097 02473100	**Hadlima**	adalimumab	40 mg/0.8 mL	Injection
02533472 02533480	**Hadlima**	adalimumab	40 mg/0.4 mL	Injection
02502380	**Hulio**	adalimumab	20 mg/0.4 mL	Injection
02502399 02502402	**Hulio**	adalimumab	40 mg/0.8 mL	Injection
02492156 02492164 02505258 02542358 02542366 02542323 02542331 02542315	**Hyrimoz**	adalimumab	40 mg/0.8 mL 40 mg/0.8 mL 20 mg/0.4 mL 80mg/0.8 mL 80mg/0.8 mL 40mg/0.4mL 40mg/0.4mL 20mg/0.2mL	Injection
02502674	**Idacio**	adalimumab	40 mg/0.8 mL	Injection
02502682	**Idacio**	adalimumab	40 mg/0.8 mL	Pre-filled Syringe
02523949 02523957	**Simlandi**	adalimumab	40 mg/0.4 mL	Injection
02523965	**Simlandi**	adalimumab	80 mg/0.8 mL	Injection
02523760 02523779	**Yuflyma**	adalimumab	40 mg/0.8 mL	Injection
02535084 02535076	**Yuflyma**	adalimumab	80 mg/0.8 mL	Injection

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.

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.

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.

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.

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

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

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

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.

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.

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.

02460521 02460548 02472961 02472988	**Kevzara**	sarilumab	150 mg/1.14 mL 200 mg/1.14 mL 150 mg/1.14 mL 200 mg/1.14 mL	Injection

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	**Kineret**	anakinra	150 mg/mL	Injection

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

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

02539861	**Omvoh**	mirikizumab	20 mg/mL	Solution intravenous
02539853	**Omvoh**	mirikizumab	100 mg/mL	Injection prefilled syringe
02539845	**Omvoh**	mirikizumab	100 mg/mL	Injection prefilled pen
02506009	**Zeposia**	ozanimod	0.23mg & 0.46mg	Capsules (initiation pack)
02505991	**Zeposia**	ozanimod	0.92mg	Capsule

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.

02495155	**Rinvoq**	upadacitinib	15 mg	Tablet

Ankylosing Spondylitis
For the treatment of adults with active ankylosing spondylitis (AS) who have had an inadequate response to a biologic disease-modifying antirheumatic drug (bDMARD) or when use of those therapies is inadvisable[1], only if the following criteria are met:

Patients have previously 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.

Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.

[1]Scenarios of patients for whom use of bDMARDS are inadvisable include patients who were intolerant to, or who have contraindications to, bDMARDS for AS.

Rheumatoid Arthritis
For the treatment of patients 18 years of age or older who have moderate to severe active rheumatoid arthritis and have:
(a) failed treatment with at least 3 DMARD therapies, one of which is methotrexate or leflunomide or both, unless intolerance or contraindications to these agents is documented;
(b) tried one combination therapy of DMARDs; and
(c) documented disease activity (such as the number of tender joints, the number of swollen joints, the erythrocyte sedimentation rate or C-reactive protein value).

NOTE: Coverage will be provided only if prescribed by a specialist in rheumatology.
Combined use with other biologic drugs or Janus kinase (JAK) inhibitors will not be reimbursed.

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.

Combined use with other biologic drugs or Janus kinase (JAK) inhibitors will not be reimbursed.

02495155 02520893 02539721	**Rinvoq**	upadacitinib	15 mg 30 mg 45 mg	Tablet

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.

Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.

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

Note: Coverage will be provided only if prescribed by a specialist in gastroenterology.

Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.

2480018	**Olumiant**	baricitinib	2 mg	Tablet

For the treatment of patients 18 years of age or older who have moderate to severe active rheumatoid arthritis and have:
(a) failed treatment with at least 3 DMARD therapies, one of which is methotrexate or leflunomide or both, unless intolerance or contraindications to these agents is documented;
(b) tried one combination therapy of DMARDs; and
(c) documented disease activity (such as the number of tender joints, the number of swollen joints, the erythrocyte sedimentation rate or C-reactive protein value).

NOTE: Coverage will be provided only if prescribed by a specialist in rheumatology.

Combined use with other biologic drugs or Janus kinase (JAK) inhibitors will not be reimbursed.

02470608	**Xeljanz XR**	tofacitinib	11 mg	Tablet

For the treatment of patients 18 years of age or older who have moderate to severe active rheumatoid arthritis and have:
(a) failed treatment with at least 3 DMARD therapies, one of which is methotrexate or leflunomide or both, unless intolerance or contraindications to these agents is documented;

(b) tried one combination therapy of DMARDs; and
(c) documented disease activity (such as the number of tender joints, the number of swollen joints, the erythrocyte sedimentation rate or C-reactive protein value).

NOTE: Coverage will be provided only if prescribed by a specialist in rheumatology.
Combined use with other biologic drugs or Janus kinase (JAK) inhibitors will not be reimbursed.

02498316	**Riximyo**	rituximab	10 mg/mL	Injection
02495724	**Ruxience**	rituximab	10 mg/mL	Injection
02478382 02478390	**Truxima**	rituximab	100 mg/10 mL 500 mg/50 mL	Injection

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

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.

02424770 02483327	**Actemra**	tocilizumab	162 mg/0.9 mL 162 mg/0.9 mL	Injection

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.

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.

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.

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

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.

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.

02324776 02324784 02413175 02413183	**Simponi**	golimumab	50 mcg/0.5 mL 50 mcg/0.5 mL 100 mg/1 mL 100 mg/1 mL	Injection

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.

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.

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	**Simponi IV**	golimumab	50 mg/4 mL	Injection

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

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

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.

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.

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

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

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

02516098	**Ilumya**	tildrakizumab	100 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.

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

Psoriasis

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

• Psoriasis Area and the Severity Index (PASI) ≥ 10
• Body Surface Area (BSA) > 10%
• Significant involvement of the face, hands feet or genital region
• Dermatology Life Quality Index (DLQI) > 10 AND
• Failure to respond to, contraindications to, intolerant of or unable to access methotrexate, cyclosporine and/or phototherapy.

Coverage will be approved initially for a maximum of 3 months. For continued coverage the physician must confirm the patient's response to treatment and demonstration of treatment clinical benefits:

• ≥ 50% reduction in the PASI score with ≥ 5 point improvement in the DLQI
• ≥ 75 % reduction in the PASI score
• ≥ 50% reduction in the BSA with significant improvement of the face, hands, feet or genital region.

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

Jamteki or Wezlana will be the preferred ustekinumab option for all ustekinumab-naive patients prescribed an ustekinumab product for Psoriasis. Preferred means the first ustekinumab product to be considered for reimbursement for ustekinumab-naive patients. Patients will not be permitted to switch from Stelara, Jamteki or Wezlana to another ustekinumab product or vice versa, if previously trialed and deemed unresponsive to ustekinumab.

02543036 02543044	**Jamteki**	ustekinumab	45 mg/0.5 mL 90 mg/1 mL	Injection

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.

Psoriasis
For treatment of adult patients with severe plaque psoriasis presently with one or more of the following:
• Psoriasis Area and the Severity Index (PASI) ≥ 10
• Body Surface Area (BSA) > 10%
• Significant involvement of the face, hands, feet or genital region
• Dermatology Life Quality Index (DLQI) > 10 AND
• Failure to respond to, contraindications to, intolerant of or unable to access methotrexate, cyclosporine and/or phototherapy.
Coverage will be approved initially for a maximum of 3 months. For continued coverage the physician must confirm the patient's response to treatment and demonstration of treatment clinical benefits:
• ≥ 50% reduction in the PASI score with ≥ 5 point improvement in the DLQI
• ≥ 75 % reduction in the PASI score
• ≥ 50% reduction in the BSA with significant improvement of the face, hands, feet or genital region.

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

Jamteki will be a preferred ustekinumab option for all ustekinumab-naïve patients prescribed an ustekinumab product for Psoriasis. Preferred means the first ustekinumab product to be considered for reimbursement for ustekinumab-naive patients. Patients will not be permitted to switch from Jamteki to another ustekinumab product or vice versa, if:
• Previously trialed and deemed unresponsive to ustekinumab

02550245 02550253	**Steqeyma**	ustekinumab	45 mg/0.5 mL 90 mg/1 mL	Injection

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

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.

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

• Psoriasis Area and the Severity Index (PASI) ≥ 10
• Body Surface Area (BSA) > 10%
• Significant involvement of the face, hands, feet or genital region
• Dermatology Life Quality Index (DLQI) > 10 AND
• Failure to respond to, contraindications to, intolerant of or unable to access methotrexate, cyclosporine and/or phototherapy.

Coverage will be approved initially for a maximum of 3 months. For continued coverage the physician must confirm the patient's response to treatment and demonstration of treatment clinical benefits:

• ≥ 50% reduction in the PASI score with ≥ 5 point improvement in the DLQI
• ≥ 75 % reduction in the PASI score
• ≥ 50% reduction in the BSA with significant improvement of the face, hands, feet or genital region.

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

Steqeyma will be a preferred ustekinumab option for all ustekinumab-naïve patients prescribed an ustekinumab product for Psoriasis. Preferred means the first ustekinumab product to be considered for reimbursement for ustekinumab-naive patients. Patients will not be permitted to switch from Steqeyma to another ustekinumab product or vice versa, if:
• Previously trialed and deemed unresponsive to ustekinumab.

02550261	**Steqeyma IV**	ustekinumab	5 mg/mL	Solution

Crohn's Disease
For treatment of moderate to severely active Crohn's Disease in adult 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.

02544180	**Wezlana**	ustekinumab	45 mg/0.5 mL	Pre-filled Syringe
02544199	**Wezlana**	ustekinumab	90 mg/mL	Pre-filled Syringe
02544202	**Wezlana**	ustekinumab	45 mg/0.5 mL	Injection Single-use Vial

Crohn’s Disease
For treatment of moderate to severely active Crohn's Disease in adult 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.

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.

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

- Psoriasis Area and the Severity Index (PASI) ≥ 10
- Body Surface Area (BSA) > 10%
- Significant involvement of the face, hands, feet or genital region
- Dermatology Life Quality Index (DLQI) > 10 AND
- Failure to respond to, contraindications to, intolerant of or unable to access methotrexate, cyclosporine and/or phototherapy.

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

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

Wezlana will be a preferred ustekinumab option for all ustekinumab-naïve patients prescribed an ustekinumab product for Psoriasis. Preferred means the first ustekinumab product to be considered for reimbursement for ustekinumab-naive patients. Patients will not be permitted to switch from Wezlana to another ustekinumab product or vice versa, if:
• Previously trialed and deemed unresponsive to ustekinumab.

02544210	**Wezlana I.V.**	ustekinumab	5 mg/mL	Intavenous Solution

Crohn's Disease
For treatment of moderate to severely active Crohn's Disease in adult 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

02438070	**Cosentyx**	secukinumab	150 mg/mL	Injection
02525569	**Cosentyx**	secukinumab	75 mg/mL	Injection
02547724	**Cosentyx**	secukinumab	150 mg/mL	Pre-Filled Syringe

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.

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

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

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

Psoriatic Arthritis
For 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.

02525267	**Bimzelx**	bimekizumab	160 mg/mL	Prefilled Syringe
02525275	**Bimzelx**	bimekizumab	160 mg/mL	Autoinjector

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.

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

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

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

Request for coverage must be made by a specialist in dermatology

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

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

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

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

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

Request for coverage must be made by a specialist in rheumatology

02487314	**Tremfya**	guselkumab	100 mg/mL	Autoinjector
02469758	**Tremfya**	guselkumab	100 mg/mL	Pre-filled Syringe

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

Coverage will be approved initially for a maximum of 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

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.

02487454	**Skyrizi**	risankizumab	90 mg/mL	Injection
02519283 02519291	**Skyrizi**	risankizumab	150 mg/mL	Injection

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

- Psoriasis Area and the Severity Index (PASI) ≥ 10
- Body Surface Area (BSA) > 10%
- Significant involvement of the face, hands feet or genital region
- Dermatology Life Quality Index (DLQI) > 10 AND
- Failure to respond to, contraindications to, intolerant of or unable to access methotrexate, cyclosporine and/or phototherapy.

Coverage will be approved initially for a maximum of 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.

02532107	**Skyrizi**	risankizumab	60 mg/mL	Injection
02532093	**Skyrizi**	risankizumab	360 mg/2.4 mL	Pre-filled Cartrige with On-Body Injector

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.

02522845	**Saphnelo**	anifrolumab	150mg/mL	Injection

For the treatment of adult patients with moderate to severe autoantibody positive, systemic lupus erythematosus (SLE), only if the following criteria are met:

Initiation Criteria:
• Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score of at least 6 prior to treatment initiation with anifrolumab; AND
• Inadequately controlled with oral corticosteroids (OCS) at a dose of at least 10 mg/day of prednisone or its equivalent, in addition to standard therapy[1].

The pre-treatment baseline SLEDAI-2K score must be provided. If the British Isles Lupus Activity Group (BILAG)-2004 will be used for assessment on renewal, then a pre-treatment baseline BILAG-2004 assessment of organ systems must also be provided. The same scale should be used both at baseline and all subsequent renewals.

Initial approval: 12 months

Exclusion Criteria:
• Severe or unstable neuropsychiatric SLE; OR
• Active severe SLE nephritis

Renewal Criteria:
• Decrease in OCS dose to ≤ 7.5 mg/day of prednisone or its equivalent[2]; AND
• Reduction in disease activity as measured by:
  o R eduction in the SLEDAI-2K score to 5 or less; OR
  o BILAG-2004 score improvement[3] in organ systems and no new worsening[4].

Subsequent Renewal Criteria:
Initial response achieved after the first 12 months of therapy with anifrolumab has been maintained.

Renewal approval: 12 months

[1]Standard therapy includes using an immunosuppressive drug (e.g., azathioprine, hydroxychloroquine, methotrexate, mycophenolate) with or without non-steroidal anti-inflammatory drugs (NSAIDs).
[2]Patients whose OCS dose remains > 7.5 mg/day of prednisone or equivalent but has decreased by at least 50% from baseline could be considered to have achieved the OCS dose reduction.
[3]BILAG improvement in organ systems is defined as a reduction of all baseline severe (BILAG-2004 A) or moderately severe (BILAG-2004 B) to lower rating levels.
[4]BILAG worsening in organ systems is defined as ≥ 1 new BILAG-2004 A or ≥2 new BILAG-2004 B items.

Combined use with other biologics for the treatment of SLE will not be reimbursed.

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

02370050 02370069	**Benlysta**	belimumab	120mg/5mL 400mg/20mL	Injection
02470489	**Benlysta**	belimumab	200 mg/mL	Auto-Injector

For the treatment of active lupus nephritis (LN) in adult patients who meet all of the following criteria:
• Diagnosed with International Society of Nephrology/Renal Pathology Society class III (with or without class V), class IV (with or without class V), or class V (i.e., pure class V) LN;
• Have started standard induction therapy within the previous 60 days;
• Have not previously failed both cyclophosphamide and mycophenolate induction therapies;
• Have not had an estimated glomerular filtration rate (eGFR) that is less than 30 mL/min/1.73 m^2.

Initial approval: 12 months

Renewal Criteria:
Renewal requests must provide proof of beneficial clinical effect, including all of the following:
• Reduction in glucocorticoids to less than or equal to 7.5 mg/day of prednisone or its equivalent after 12 months of therapy (oral corticosteroid dose that remains higher than 7.5 mg/day of prednisone or its equivalent, but has decreased by at least 50% from baseline could be considered as having achieved the oral corticosteroid dose reduction); AND
• An eGFR that is greater than or equal to 60 mL/min/1.73 m^2, or that is no more than 20% below the value before the renal flare (pre-flare value); AND
• Improvement in proteinuria defined as either:
  • Proteinuria no greater than 0.7 g/24 hours after 12 months of therapy if baseline proteinuria is less than 3.5 g/24 hours; OR
  • Proteinuria no greater than 0.7 g/24 hours after 18 to 24 months of therapy if baseline

proteinuria is in the nephrotic range (i.e., greater than 3.5 g/24 hours); AND

• Have not had an eGFR decrease to less than 30 mL/min/1.73 m^2; AND

• Have not had the addition of other immunosuppressant agents (other than as part of the induction and maintenance regimens), corticosteroid use outside of the limits, anti–tumour necrosis factor therapy (such as rituximab, abatacept).

Subsequent renewal requests will be considered if the initial response in the first 12 months of therapy has been maintained.

Renewal approval: 12 months

Request for coverage must be made by a specialist in rheumatology or nephrology with experience in the management of lupus nephritis.

02416328	**Aubagio**	teriflunomide	14 mg	Tablet
02500639	**Apo-Teriflunomide**	teriflunomide	14 mg	Tablet
02504170	**Jamp Teriflunomide**	teriflunomide	14 mg	Tablet
02523833	**M-Teriflunomide**	teriflunomide	14 mg	Tablet
02500469	**Mar-Teriflunomide**	teriflunomide	14 mg	Tablet
02500310	**NAT-Teriflunomide**	teriflunomide	14 mg	Tablet
02500434	**pms-Teriflunomide**	teriflunomide	14 mg	Tablet
02505843	**Sandoz Teriflunomide**	teriflunomide	14 mg	Tablet
02501090	**Teva-Teriflunomide**	teriflunomide	14 mg	Tablet
02269201	**Avonex**	interferon beta 1-a	30 mcg/0.5 mL	Injection
02418320	**Lemtrada**	alemtuzumab	12 mg/1.2 mL	Solution for IV Infusion
02237319	**Rebif**	interferon beta 1-a	22 mcg/0.5 mL	Injection
02237320	**Rebif**	interferon beta 1-a	44 mcg/0.5 mL	Injection
02318253	**Rebif**	interferon beta 1-a	66 mcg/1.5mL	Injection
02318261	**Rebif**	interferon beta 1-a	132 mcg/1.5mL	Injection
02169649	**Betaseron**	interferon beta 1-b	0.3 mg	Injection
02365480	**Gilenya**	fingolimod	0.5 mg	Capsule
02469936	**Apo-Fingolimod**	fingolimod	0.5 mg	Capsule
02487772	**Jamp-Fingolimod**	fingolimod	0.5 mg	Capsule
02474743	**Mar-Fingolimod**	fingolimod	0.5 mg	Capsule
02469715	**Mylan-Fingolimod**	fingolimod	0.5 mg	Capsule
02469782	**pms-Fingolimod**	fingolimod	0.5 mg	Capsule
02482606	**Sandoz-Fingolimod**	fingolimod	0.5 mg	Capsule
02469618	**Taro-Fingolimod**	fingolimod	0.5 mg	Capsule

02469561	**Teva-Fingolimod**	fingolimod	0.5 mg	Capsule
02467224	**Ocrevus**	ocrelizumab	30 mg/mL	Injection
02444399 02444402	**Plegridy**	peginterferon beta-1a	125 mcg/0.5 mL 63 mcg.0.5 mL	Injection
02404508 02420201	**Tecfidera**	dimethyl fumarate	120 mg 240 mg	Capsule
02495341 02495368	**ACH-Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Capsule
02505762 02505770	**Apo-Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Capsule
02540746 02540754	**Auro-Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Capsule
02494809 02494817	**GLN-Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Capsule
02516047 02516055	**Jamp Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Capsule
02502690 02502704	**Mar-Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Capsule
02497026 02497034	**pms-Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Capsule
02513781 02513803	**Sandoz Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Capsule
02286386	**Tysabri**	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.

02460661	**Glatect**	glatiramer acetate	20 mg/mL	Pre-Filled Syringe
02541440	**Glatiramer Acetate Injection**	glatiramer acetate	20 mg/mL	Pre-Filled Syringe

For the treatment of patients who have relapsing-remitting multiple sclerosis (RRMS), when prescribed by a neurologist from the Manitoba Multiple Sclerosis (MS) Clinic, and:
- Patient must have met diagnostic criteria for MS, as per the revised McDonald criteria
- Patient must be 18 years or older
- The course of disease must include at least one recent clinical attack in the year prior to therapy or two attacks in the previous two years
- The patient must still be ambulatory (with aids, if necessary).

02511355	**Kesimpta**	ofatumumab	20 mg/0.4 mL	Injection

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	**Mavenclad**	cladribine	10 mg	Tablet

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

02244550 02244552	**Pamidronate Disodium**	pamidronate disodium	3 mg/mL 9 mg/mL	Injection
02249685	**Pamidronate Disodium Omega**	pamidronat+A1698:C1721 edisodium	9 mg/mL	Injection

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

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

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

02485877 02485885 02485893	**Envarsus PA**	tacrolimus	0.75 mg 1 mg 4 mg	Extended Release Tablet

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

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

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

02264560 02264579	**Myfortic**	mycophenolate sodium	180 mg 360 mg	Tablet
02372738 02372746	**Apo-Mycophenolic Acid**	mycophenolate sodium	180 mg 360 mg	Tablet
02511673 02511681	**Mar-Mycophenolic Acid**	mycophenolic sodium	180 mg 360 mg	Tablet

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

00718149	**Tryptan**	l-tryptophan	500 mg	Capsule
02029456 00654531	**Tryptan**	l-tryptophan	500 mg 1 g	Tablet

02248540	**Apo-Tryptophan**	l-tryptophan	500 mg	Capsule
02248538 02458721 02248539	**Apo-Tryptophan**	l-tryptophan	500 mg 750 mg 1 g	Tablet
02240334	**TEVA-Tryptophan**	l-tryptophan	500 mg	Capsule
02240333 02237250	**TEVA-Tryptophan**	l-tryptophan	500 mg 1 g	Tablet

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

02241888 02241889	**Arava**	leflunomide	10 mg 20 mg	Tablet
02478862 02478870	**Accel-Leflunomide**	leflunomide	10 mg 20 mg	Tablet
02256495 02256509	**Apo-Leflunomide**	leflunomide	10 mg 20 mg	Tablet
02351668 02351676	**Leflunomide**	leflunomide	10 mg 20 mg	Tablet
02543575 02543583	**Leflunomide**	leflunomide	10 mg 20 mg	Tablet
02551918 02551926	**MAR-Leflunomide**	leflunomide	10 mg 20 mg	Tablet
02261251 02261278	**Teva-Leflunomide**	leflunomide	10 mg 20 mg	Tablet
02283964 02283972	**Sandoz Leflunomide**	leflunomide	10 mg 20 mg	Tablet

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

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

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

02441489 02454548	**Grastofil**	filgrastim	300 mcg/0.5 mL 480 mcg/0.8 mL	Injection
02485575 02485583 02485591 02485656	**Nivestym**	filgrastim	300 mcg/0.5 mL 480 mcg/0.8 mL 300 mcg/mL 480 mcg/1.6 mL	Injection
02520990 02521008	**Nypozi**	filgrastim	300 mcg/0.5 mL 480 mcg/0.8 mL	Injection

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

02387174	**Dificid**	fidaxomicin	200 mg	Tablet

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

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

02464489 02464500	**Esbriet**	pirfenidone	267 mg 801 mg	Tablet
02509938	**Jamp Pirfenidone**	pirfenidone	267 mg	Capsules
02514702 02514710	**Jamp Pirfenidone**	pirfenidone	267 mg 801 mg	Tablets
02550644 02550652	**M-Pirfenidone**	pirfenidone	268 mg 801 mg	Tablets
02531526 02531534	**pms-Pirfenidone**	pirfenidone	267 mg 801 mg	Tablets
02488833	**Sandoz Pirfenidone**	pirfenidone	267 mg	Capsules
02488507 02488515	**Sandoz Pirfenidone**	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	**Ofev**	nintedanib	100 mg 150 mg	Capsule

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

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.

02242471	**Dostinex**	cabergoline	0.5 mg	Tablet
02455897	**Apo-Cabergoline**	cabergoline	0.5 mg	Tablet

For treatment of:
a) Hyperprolactinemic disorders in patients unresponsive to bromocriptine.
b) Hyperprolactinemic disorders in patients intolerant to bromocriptine.

RESPIRATORY TRACT AGENTS

02470365 02492504 02510049 02524252	**Dupixent**	dupilumab	150 mg/mL 200 mg/1.14 mL 150 mg/mL 200 mg/1.14 mL	Injection

As add-on maintenance treatment for patients 6 to 11 years of age with severe asthma with a type 2/eosinophilic phenotype, if the following criteria are met:
Initiation criteria
• Patient must have a documented diagnosis of severe asthma with a type 2/eosinophilic phenotype; AND
• Symptoms not controlled despite optimal treatment, defined as daily use of medium- to high-dose inhaled corticosteroids (ICS)1 plus one controller medication (e.g., long-acting beta-agonists (LABA)); AND
• Blood eosinophil count of ≥ 150 cells/μL within the past 12 months; AND
• Uncontrolled asthma with at least one clinically significant asthma exacerbation[2] in the past 12 months.
Administration criteria
• Dupilumab should not be used in combination with other biologics used to treat asthma.

- A baseline assessment of asthma symptom control using a validated asthma control questionnaire must be completed prior to initiation of dupilumab treatment.
- The initial prescription of dupilumab should be by a pediatric respirologist or allergist. Patients should be managed by a physician with expertise in treating asthma in pediatric patients.

[1]High-dose ICS is defined as greater or equal to 400mcg of fluticasone propionate or equivalent daily. Medium-dose ICS is defined as greater than 100 mcg-400 mcg of fluticasone propionate or equivalent daily.

[2]Clinically significant asthma exacerbations are defined as worsening of asthma resulting in hospitalization, an emergency care visit, or treatment with systemic corticosteroids.

Renewal criteria
- The effects of treatment should be assessed every 12 months to determine whether reimbursement should continue.
- Reimbursement of treatment should be discontinued if:
  - The 12 month asthma control questionnaire score has not improved from baseline, when baseline represents the initiation of treatment; OR
  - The asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently; OR
  - The number of clinically significant asthma exacerbations has increased within the previous 12 months.

As add-on maintenance treatment for patients aged 12 years and older with severe asthma with a type 2/eosinophilic phenotype if the following criteria are met:

Initiation Criteria:
- Patient must have a documented diagnosis of severe asthma with a type 2/eosinophilic phenotype.
- 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).
- Patient has one of the following:
  - Blood eosinophil count of ≥ 300 cells/µL within the past 12 months AND has experienced two or more clinically significant asthma exacerbations[1] in the past 12 months, OR
  - Blood eosinophil count of ≥ 150 cells/µL AND is receiving maintenance treatment with oral corticosteroids (OCS)

Administration Criteria:
- Dupilumab should not be used in combination with other biologics used to treat asthma.
- A baseline assessment of asthma symptom control using a validated asthma control questionnaire must be completed prior to initiation of dupilumab treatment.
- Patients should be managed by a physician with expertise in treating asthma.

[1] Clinically significant asthma exacerbations are defined as worsening of asthma resulting in administration of systemic corticosteroids for at least three days, or hospitalization.

Renewal Criteria:
- The effects of treatment should be assessed every 12 months to determine

whether reimbursement should continue.
- Reimbursement of treatment should be discontinued if:
  - The 12 month asthma control questionnaire score has not improved from baseline, when baseline represents the initiation of treatment; OR
  - The asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently; OR
  - The number of clinically significant exacerbations has increased within the previous 12 months; OR
  - In patients on maintenance treatment with OCS, there has been no decrease in the OCS dose in the first 12 months of treatment; OR
  - 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.

02473232 02496135	**Fasenra**	benralizumab	30 mg/mL	Injection

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 ≥ 300 cells/µL AND has experienced two or more clinically significant asthma exacerbations in the past 12 months, OR
   3.2. blood eosinophil count of ≥ 150 cells/µL 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.

02492989 02492997	**Nucala**	mepolizumab	100mg/ml	Injection

Eosinophilic Asthma

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 ≥ 300 cells/µL AND has experienced two or more clinically significant asthma exacerbations in the past 12 months, OR
   - 3.2. blood eosinophil count of ≥ 150 cells/µL AND is receiving maintenance treatment with oral corticosteroids (OCS).

Administration Criteria

1. Mepolizumab 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 mepolizumab 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.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

For add-on maintenance treatment with intranasal corticosteroids in adult patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP) inadequately controlled by intranasal corticosteroids alone, only if the following criteria are met:

Initiation Criteria

1. Patients must have ALL of the following:
• endoscopically or CT-documented bilateral nasal polyps
• have undergone at least 1 prior surgical intervention for nasal polyps or have a contraindication to surgery
• be tolerant and able to continue use of inhaled nasal corticosteroids but have refractory symptoms despite use of inhaled corticosteroids for 3 months at maximally tolerated doses.
2. A baseline Sino-nasal Outcome Test-22 (SNOT-22) or endoscopic nasal polyp score (NPS) must be provided with the initial request for coverage.

Initial approval: 1 year

Renewal Criteria

Patients must exhibit a clinically meaningful response* on the SNOT-22 or endoscopic NPS relative to their baseline score.

*A clinically meaningful response on the SNOT-22 is a decrease in score from baseline of 8.9 points or greater. A clinically meaningful response for NPS is a decrease in score from baseline of 1 point or greater.

Renewal approval: 1 year

Request for coverage must be made by a physician with expertise in managing severe CRSwNP (for example, otolaryngologist, allergist, respirologist).

02529548	**Tezspire**	ezepelumab	110mg/mL	Pre-filled Syringe
02529556	**Tezspire**	ezepelumab	110mg/mL	Pre-filled Pen

As an add-on maintenance treatment for patients aged 12 years and older with severe asthma, if all the following criteria are met:

Initiation criteria:

• Asthma inadequately controlled with high-dose inhaled corticosteroids (ICS), 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 [LABA]).
• Patient has experienced two or more clinically significant asthma exacerbations[1] in the past 12 months.

Administration criteria:

• Tezepelumab should not be used in combination with other biologics used to treat asthma.
• A baseline assessment of asthma symptom control using a validated asthma control questionnaire must be completed prior to initiation of tezepelumab treatment.
• Tezepelumab should be initiated and monitored by an allergist or respirologist with experience managing severe asthma.

[1]Clinically significant asthma exacerbations are defined as worsening of asthma resulting in administration of systemic corticosteroids for at least three days, or hospitalization.

Renewal criteria:

• The effects of treatment should be assessed every 12 months to determine whether reimbursement should continue.
• Reimbursement of treatment should be discontinued if:

o The 12-month asthma control questionnaire score has not improved from baseline, when baseline represents the initiation of treatment; OR
o The asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently; OR
o The number of clinically significant asthma exacerbations has increased within the previous 12 months; OR
o In patients on maintenance treatment with oral corticosteroids (OCS), there has been no decrease in the OCS dose in the first 12 months of treatment; OR
o 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 or improved subsequently.

ANTI-INFECTIVE AGENTS				
02239630	**Tobi**	tobramycin	60 mg/mL	Inhalation Solution
02389622	**Teva-Tobramycin**	tobramycin	60 mg/mL	Inhalation Solution

For the treatment of chronic pulmonary pseudomonas infections in patients with cystic fibrosis (CF).