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

Updated: June 22, 2023
NOTES REGARDING THE EXCEPTION DRUG STATUS (EDS) PROGRAM:

- Duly licensed practitioners prescribing within their scope of practice may apply for EDS.
- Requests can be submitted by mail or by fax. The fax number is (204) 942-2030 or 1-877-208-3588. These numbers are for health professionals only.
- To ensure eligible benefit coverage, approval must take place prior to purchase or dispensing of a prescription drug. Retroactive coverage is not provided, no exceptions.
- EDS requests are prioritized by date received and the urgency of the request.
- To ensure continuity of coverage, requests for renewal should be forwarded prior to the expiry date. Please allow at least one to two business days. Urgent requests received during regular business hours will usually be processed within 24 hours.
- Patients are notified by letter if a request for coverage has been approved or denied.
- If a drug is approved for coverage under EDS, coverage is valid from the date of application to date of expiration.
- If denied, payment for the medication is the responsibility of the patient.
- For NEW requests - If a client meets EDS criteria for one of the products identified in the List of Designated Drugs with Indefinite EDS Approval, benefit coverage will be granted indefinitely. The client will receive an initial approval letter which confirms indefinite EDS approval.
- For RENEWAL requests - If a client has an active EDS approval for a product identified in the List of Designated Drugs with Indefinite EDS Approval – as of October 1, 2017, this coverage will be grandfathered indefinitely; no renewal will be required. The client will not be sent a letter to confirm their continued EDS approval.
- If the request for benefit coverage is not approved, payment for the medication is the responsibility of the patient.

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

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

PRODUCT SELECTION:

In September 2001, F/P/T Health Ministers agreed to establish a single Common Drug Review (CDR) for new drugs (chemical entities) submitted in Canada for coverage by F/P/T drug plans. Beginning September 2003, all new drugs are reviewed nationally through the CDR process, with expert advice and recommendations being provided by the Canadian Agency for Drugs and Technologies in Health (CADTH). The recommendations of CADTH are taken into consideration by each jurisdiction when making a listing decision.

CADTH recommendations are taken into account by the Manitoba Drug Standards and Therapeutics Committee who makes recommendations to the Minister of Health on drug products to be considered for benefit under the Pharmacare Drug Benefit Program.

Committee members provide recommendations on drug interchangeability and on the therapeutic and economic value of drug benefits.

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

For more information on the Manitoba Drug Benefits Formulary and the Manitoba Drug Interchangeability Form http://www.gov.mb.ca/health/mdbif/
PROVINCIAL DRUG PROGRAMS REVIEW PROCESS (SPECIAL CIRCUMSTANCES):

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

Please address request to:

Provincial Drug Programs Review Committee
300 Carlton Street – Room 1070
Winnipeg MB R3B 3M9
Fax (204) 942-2030 or 1-877-208-3588

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

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

CRITERIA:

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

ANTIHYPERTENSIVE/ANTILIPIDEMIC DRUGS

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand Name</th>
<th>Dosage</th>
<th>Form</th>
</tr>
</thead>
<tbody>
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<td>10/10 mg</td>
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<td>02273276</td>
<td></td>
<td>5/80 mg</td>
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<td>02273314</td>
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<td>10/80 mg</td>
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<td>02411253</td>
<td>Apo-Amlodipine/Atorvastatin</td>
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<tr>
<td>02362821</td>
<td></td>
<td>10/80 mg</td>
<td></td>
</tr>
</tbody>
</table>

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.
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 than 5.6 mmol/L, measured within the preceding 3 months before starting treatment with icosapent ethyl, 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.

**AUTONOMIC DRUGS**

<table>
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<tr>
<th>Code</th>
<th>Drug Name</th>
<th>Formulation</th>
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<td>Exelon</td>
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<td>02242116</td>
<td>Exelon</td>
<td>rivastigmine 3 mg</td>
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<tr>
<td>02242117</td>
<td>Exelon</td>
<td>rivastigmine 4.5 mg</td>
</tr>
<tr>
<td>02242118</td>
<td>Exelon</td>
<td>rivastigmine 6 mg</td>
</tr>
<tr>
<td>02245240</td>
<td>Exelon</td>
<td>rivastigmine 2 mg/mL</td>
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<td>02336715</td>
<td>Apo-Rivastigmine</td>
<td>rivastigmine 1.5 mg</td>
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<tr>
<td>02336723</td>
<td>Apo-Rivastigmine</td>
<td>rivastigmine 3 mg</td>
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<td>Apo-Rivastigmine</td>
<td>rivastigmine 4.5 mg</td>
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<tr>
<td>02336758</td>
<td>Apo-Rivastigmine</td>
<td>rivastigmine 6 mg</td>
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<td>02401614</td>
<td>Med-Rivastigmine</td>
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<tr>
<td>02401622</td>
<td>Med-Rivastigmine</td>
<td>rivastigmine 3 mg</td>
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<tr>
<td>02401630</td>
<td>Med-Rivastigmine</td>
<td>rivastigmine 4.5 mg</td>
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<tr>
<td>02401649</td>
<td>Med-Rivastigmine</td>
<td>rivastigmine 6 mg</td>
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<td>02324563</td>
<td>Sandoz Rivastigmine</td>
<td>rivastigmine 1.5 mg</td>
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<td>02324571</td>
<td>Sandoz Rivastigmine</td>
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<td>02324598</td>
<td>Sandoz Rivastigmine</td>
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</tr>
<tr>
<td>02324601</td>
<td>Sandoz Rivastigmine</td>
<td>rivastigmine 6 mg</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>02518058</th>
<th>Breztri Aerosphere</th>
<th>budesonide/glycopyrronium/fomoterol</th>
<th>182/8.2/5.8 mcg</th>
<th>Metered Dose Inhaler</th>
</tr>
</thead>
</table>
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

<table>
<thead>
<tr>
<th>02501244</th>
<th>Enerzair Breezhaler</th>
<th>glycopyrronium/indacaterol/mometasone furoate</th>
<th>50/150/160 mcg</th>
<th>Capsule</th>
</tr>
</thead>
</table>
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.

<table>
<thead>
<tr>
<th>02474522</th>
<th>Trelegy Ellipta</th>
<th>fluticasone furoate/umeclidinium/vilanterol</th>
<th>100 mcg/62.5 mcg/25 mcg</th>
<th>Powder for Inhalation</th>
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</table>
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

<table>
<thead>
<tr>
<th>02532247 02532255 02532263 02532271 02532298</th>
<th>Elonox</th>
<th>enoxaparin sodium</th>
<th>30 mg/0.3 mL 40 mg/0.4 mL 60 mg/0.6 mL 80 mg/0.8 mL 100 mg/mL</th>
<th>Injection</th>
</tr>
</thead>
</table>
02532301 02532328 | Elonox HP | enoxaparin sodium | 120 mg/0.8 mL 150 mg/mL | Injection |
<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Active Ingredient</th>
<th>Dose Options</th>
<th>Type</th>
</tr>
</thead>
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<tr>
<td>02132621</td>
<td>Fragmin</td>
<td>dalteparin</td>
<td>2500 IU/0.2 mL, 3500 IU/0.28 mL, 5000 IU/0.2 mL, 10000 IU/mL, 25000 IU/mL, 18000 IU/0.72 mL, 7500 IU/0.3 mL, 15000 IU/0.6 mL, 10000 IU/0.4 mL, 12500 IU/0.5 mL</td>
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<tr>
<td>02236913</td>
<td>Fraxiparine</td>
<td>nadroparin</td>
<td>9500 IU/mL, 19000 IU/mL</td>
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<tr>
<td>02229755</td>
<td>Innohep</td>
<td>tinzaparin</td>
<td>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, 8000/0.4 mL, 12,000/0.6 mL, 16,000/0.8 mL</td>
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<tr>
<td>02507501</td>
<td>Inclunox</td>
<td>enoxaparin sodium</td>
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<td>02507560</td>
<td>Inclunox-HP</td>
<td>enoxaparin sodium</td>
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<td>Lovenox</td>
<td>enoxaparin</td>
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<tr>
<td>02506440</td>
<td>Noromby</td>
<td>enoxaparin sodium</td>
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<tr>
<td>Code</td>
<td>Product*</td>
<td>Strengths</td>
<td>Formulation</td>
<td>Notes</td>
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<td>02506505</td>
<td>Noromby HP</td>
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<td>(biosimilar)</td>
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<tr>
<td>02509075</td>
<td>Redesca</td>
<td>enoxaparin sodium</td>
<td>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</td>
<td>Injection</td>
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<tr>
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<td>(biosimilar)</td>
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</table>

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

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Xarelto</th>
<th>rivaroxaban</th>
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<tbody>
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<td>02316986</td>
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<td>10 mg</td>
<td>Tablet</td>
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</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Xarelto</th>
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<tr>
<td>02378612</td>
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<td></td>
<td>20 mg</td>
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</tr>
</tbody>
</table>

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

Exclusions:
- Patients with clinically significant active bleeding, such as gastrointestinal bleeding, including that associated with hemorrhagic manifestations, bleeding diathesis, spontaneous impairment of hemostasis or patients with spontaneous impairment of hemostasis.
- Patients with severe renal impairment (CrCl < 30 mL/min).
<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Active Ingredient</th>
<th>Strengths</th>
<th>Form</th>
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<tr>
<td>02378612</td>
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<td>20 mg</td>
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</tbody>
</table>

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).

<table>
<thead>
<tr>
<th>Code</th>
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<th>Strengths</th>
<th>Form</th>
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</tr>
<tr>
<td>02458659</td>
<td></td>
<td></td>
<td>30 mg</td>
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</tr>
<tr>
<td>02458667</td>
<td></td>
<td></td>
<td>60 mg</td>
<td></td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Active</th>
<th>Strengths</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>02477777</td>
<td>Monoferric</td>
<td>iron</td>
<td>100 mg/mL</td>
<td>Injection</td>
</tr>
</tbody>
</table>

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.
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

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.
<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
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<th>Form</th>
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</thead>
<tbody>
<tr>
<td>02445883</td>
<td>Atomoxetine</td>
<td>10 mg, 18 mg, 25 mg, 40 mg, 60 mg</td>
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</tr>
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<td>02445913</td>
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</tr>
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<td>02445948</td>
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</tr>
<tr>
<td>02506807</td>
<td>Jamp Atomoxetine</td>
<td>10 mg, 18 mg, 25 mg, 40 mg, 60 mg</td>
<td>Capsule</td>
</tr>
<tr>
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<td>Jamp Atomoxetine</td>
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<tr>
<td>02506823</td>
<td>Jamp Atomoxetine</td>
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</tr>
<tr>
<td>02506831</td>
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<tr>
<td>02506858</td>
<td>Jamp Atomoxetine</td>
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<td></td>
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<td>02386429</td>
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<tr>
<td>02314541</td>
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<tr>
<td>02314576</td>
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<tr>
<td>02314584</td>
<td>Teva-Atomoxetine</td>
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</tr>
<tr>
<td>02314592</td>
<td>Teva-Atomoxetine</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td>02284294</td>
<td>Apo-Oxcarbazepine</td>
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<tr>
<td>02284308</td>
<td>Apo-Oxcarbazepine</td>
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<tr>
<td>02284316</td>
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<tr>
<td>02242068</td>
<td>Trileptal</td>
<td>300 mg, 600 mg</td>
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<tr>
<td>02242069</td>
<td>Trileptal</td>
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<tr>
<td>02244673</td>
<td>Trileptal</td>
<td>60 mg/mL</td>
<td>Liquid</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Strengths</th>
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<tbody>
<tr>
<td>02426862</td>
<td>Aptiom</td>
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<td>02499592</td>
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<td>02478234</td>
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Updated: June 22, 2023
### Teva-Lacosamide

<table>
<thead>
<tr>
<th>Dose</th>
<th>Formulation</th>
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<tbody>
<tr>
<td>50 mg</td>
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<tr>
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<td>Tablet</td>
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<tr>
<td>150 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>200 mg</td>
<td>Tablet</td>
</tr>
</tbody>
</table>

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.

### Fycompa

<table>
<thead>
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<th>Formulation</th>
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</thead>
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<tr>
<td>2 mg</td>
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<td>4 mg</td>
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<td>10 mg</td>
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</tr>
<tr>
<td>12 mg</td>
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</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Dose (mg/mL)</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>02497859</td>
<td>Ajovy</td>
<td>fremanezumab</td>
<td>225 mg/1.5 mL, Injection</td>
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<td>02509474</td>
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</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Dose (mg/mL)</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>02491087</td>
<td>Emgality</td>
<td>galcanezumab</td>
<td>120 mg/mL, Injection</td>
</tr>
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</tbody>
</table>

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.

Updated: June 22, 2023
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

<table>
<thead>
<tr>
<th>Opiate Agonists</th>
<th>Codeine Contin</th>
<th>codeine</th>
<th>50 mg</th>
<th>100 mg</th>
<th>150 mg</th>
<th>200 mg</th>
<th>Sustained Release Tablet</th>
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<td>02230302</td>
<td>Codeine Contin</td>
<td>codeine</td>
<td>50 mg</td>
<td>100 mg</td>
<td>150 mg</td>
<td>200 mg</td>
<td>Sustained Release Tablet</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand Name</th>
<th>Active Ingredient</th>
<th>Strengths</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>02420864</td>
<td>Abilify Maintena</td>
<td>aripiprazole</td>
<td>300 mg/vL, 400 mg/vL</td>
<td>Injection</td>
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<tr>
<td>02420872</td>
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<tr>
<td>02354217</td>
<td>Invega Sustenna</td>
<td>paliperidone</td>
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<tr>
<td>02456001</td>
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</tbody>
</table>
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**

<table>
<thead>
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<th>Code</th>
<th>Brand Name</th>
<th>Active Ingredient</th>
<th>Concentration</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>02242814</td>
<td>Apo-Lactulose</td>
<td>lactulose</td>
<td>667 mg/mL</td>
<td>Oral Liquid</td>
</tr>
<tr>
<td>02295881</td>
<td>Jamp-Lactulose</td>
<td>lactulose</td>
<td>667 mg/mL</td>
<td>Oral Solution</td>
</tr>
<tr>
<td>02412268</td>
<td>Lactulose</td>
<td>lactulose</td>
<td>667 mg/mL</td>
<td>Oral Solution</td>
</tr>
<tr>
<td>0247383</td>
<td>Pharma-Lactulose</td>
<td>lactulose</td>
<td>667 mg/mL</td>
<td>Oral Solution</td>
</tr>
<tr>
<td>00703486</td>
<td>pms-Lactulose</td>
<td>lactulose</td>
<td>667 mg/mL</td>
<td>Oral Liquid</td>
</tr>
<tr>
<td>00854409</td>
<td>ratio-Lactulose</td>
<td>lactulose</td>
<td>667 mg/mL</td>
<td>Oral Liquid</td>
</tr>
</tbody>
</table>

Portal systemic encephalopathy.

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand Name</th>
<th>Active Ingredient</th>
<th>Concentration</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>02410702</td>
<td>Zaxine</td>
<td>rifaximin</td>
<td>550 mg</td>
<td>Tablet</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand Name</th>
<th>Active Ingredient</th>
<th>Concentration</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>02248151</td>
<td>Alphagan P</td>
<td>brimonidine tartrate</td>
<td>0.15%</td>
<td>Ophthalmic Solution</td>
</tr>
<tr>
<td>02301334</td>
<td>Apo-Brimonidine P</td>
<td>brimonidine tartrate</td>
<td>0.15%</td>
<td>Ophthalmic Solution</td>
</tr>
</tbody>
</table>

Intolerance to brimonidine 0.2%.

**GASTROINTESTINAL DRUGS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand Name</th>
<th>Active Ingredients</th>
<th>Concentration</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>02470780</td>
<td>Apo-Lansoprazole-Amoxicillin-Clarithromycin</td>
<td>amoxicillin/clarithromycin/lansoprazole</td>
<td>500 mg 500 mg 30 mg</td>
<td>Tablet</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Active Ingredient</th>
<th>Dosage</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>02229293</td>
<td>Entocort</td>
<td>budesonide</td>
<td>3 mg</td>
<td>Capsule</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Active Ingredient</th>
<th>Dosage</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>02391600</td>
<td>ACH-Pioglitazone</td>
<td>pioglitazone</td>
<td>15 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>0239587</td>
<td></td>
<td></td>
<td>30 mg</td>
<td>Tablet</td>
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<tr>
<td>0239595</td>
<td></td>
<td></td>
<td>45 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02302861</td>
<td>ACT Pioglitazone</td>
<td>pioglitazone</td>
<td>15 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02302888</td>
<td></td>
<td></td>
<td>30 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02302896</td>
<td></td>
<td></td>
<td>45 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02302942</td>
<td>Apo-Pioglitazone</td>
<td>pioglitazone</td>
<td>15 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02302950</td>
<td></td>
<td></td>
<td>30 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02302977</td>
<td></td>
<td></td>
<td>45 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02397307</td>
<td>Jamp-Pioglitazone</td>
<td>pioglitazone</td>
<td>15 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02365529</td>
<td></td>
<td></td>
<td>30 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02365537</td>
<td></td>
<td></td>
<td>45 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02326477</td>
<td>Mint-Pioglitazone</td>
<td>pioglitazone</td>
<td>15 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02326485</td>
<td></td>
<td></td>
<td>30 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02326493</td>
<td></td>
<td></td>
<td>45 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02303124</td>
<td>pms-Pioglitazone</td>
<td>pioglitazone</td>
<td>15 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02303132</td>
<td></td>
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<td>30 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02303140</td>
<td></td>
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<td>45 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02297906</td>
<td>Sandoz Pioglitazone</td>
<td>pioglitazone</td>
<td>15 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02297914</td>
<td></td>
<td></td>
<td>30 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02297922</td>
<td></td>
<td></td>
<td>45 mg</td>
<td>Tablet</td>
</tr>
</tbody>
</table>

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.
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.)

(a) Inadequate control on maximum doses of glyburide and metformin.
(b) Frequent or severe hypoglycemic events despite dosage adjustments of glyburide or gliclazide.
<table>
<thead>
<tr>
<th>Code</th>
<th>Product Name</th>
<th>Active Ingredient</th>
<th>Strengths (mg)</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>02531631</td>
<td>Taro-Sitagliptin Fumarate</td>
<td>sitagliptin</td>
<td>25 mg, 50 mg, 100 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02531658</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02531666</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02443937</td>
<td>Jardiance</td>
<td>empagliflozin</td>
<td>10 mg, 25 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02443945</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02375842</td>
<td>Onglyza</td>
<td>saxagliptin</td>
<td>2.5 mg, 5 mg</td>
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</tr>
<tr>
<td>02333554</td>
<td></td>
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</tr>
<tr>
<td>02507471</td>
<td>Apo-Saxagliptin</td>
<td>saxagliptin</td>
<td>2.5 mg, 5 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02507498</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02468603</td>
<td>Sandoz Saxagliptin</td>
<td>saxagliptin</td>
<td>2.5 mg, 5 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02468611</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02370921</td>
<td>Trajenta</td>
<td>linagliptin</td>
<td>5 mg</td>
<td>Tablet</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Product Name</th>
<th>Active Ingredient</th>
<th>Strengths (mg)</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>02443937</td>
<td>Jardiance</td>
<td>empagliflozin</td>
<td>10 mg, 25 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02443945</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Product Name</th>
<th>Active Ingredient</th>
<th>Strengths (mg)</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>02456575</td>
<td>Synjardy</td>
<td>empagliflozin/metformin</td>
<td>5/500 mg, 5/850 mg, 5/1000 mg, 12.5/500 mg, 12.5/850 mg, 12.5/1000 mg</td>
<td>Tablet</td>
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<tr>
<td>02456583</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02456591</td>
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<td>02456605</td>
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<tr>
<td>02456613</td>
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</tr>
<tr>
<td>02456621</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
<table>
<thead>
<tr>
<th>Code</th>
<th>Product Name</th>
<th>Active Ingredients</th>
<th>Dose Options</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0233856</td>
<td>Janumet</td>
<td>sitagliptin/metformin</td>
<td>50/500 mg 50/850 mg 50/1000 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>0233864</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0233872</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>0250415</td>
<td>Apo-Sitagliptin Malate/</td>
<td>sitagliptin/metformin</td>
<td>50/500 mg 50/850 mg 50/1000 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>0250423</td>
<td>Metformin</td>
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<tr>
<td>02509431</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02503956</td>
<td>Sandoz Sitagliptin-</td>
<td>sitagliptin/metformin</td>
<td>50/500 mg 50/850 mg 50/1000 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02503964</td>
<td>Meformin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02503972</td>
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</tr>
<tr>
<td>02416794</td>
<td>Janumet XR</td>
<td>sitagliptin/metformin</td>
<td>50/1000 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02506270</td>
<td>Apo-Sitagliptin/Metformin</td>
<td>sitagliptin/metformin</td>
<td>50/500 mg 50/1000 mg 100/1000 mg</td>
<td>Tablet</td>
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<tr>
<td>02506289</td>
<td>XR</td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>02506297</td>
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</tr>
<tr>
<td>02529106</td>
<td>Sandoz Sitagliptin-</td>
<td>sitagliptin/metformin</td>
<td>50/500 mg 50/1000 mg 100/1000 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02529114</td>
<td>Meformin XR</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>02529122</td>
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<td></td>
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</tr>
<tr>
<td>02403250</td>
<td>Jentadueto</td>
<td>linagliptin/metformin</td>
<td>2.5/500 mg 2.5/850 mg 2.5/1000 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02403269</td>
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<td></td>
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<td>02403277</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>02389169</td>
<td>Komboglyze</td>
<td>saxagliptin/metformin</td>
<td>2.5/500 mg 2.5/850 mg 2.5/1000 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02389177</td>
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<td></td>
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<td>02389185</td>
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<tr>
<td>02449935</td>
<td>Xigduo</td>
<td>dapagliflozin/metformin</td>
<td>5/850 mg 5/1000 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02449943</td>
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</tr>
<tr>
<td>02435462</td>
<td>Forxiga</td>
<td>dapagliflozin</td>
<td>5 mg 10 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02435470</td>
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</tbody>
</table>

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.

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

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

For treatment of type 2 diabetes in combination with a basal insulin with or without metformin in patients who have been uncontrolled on, or are intolerant to, a sulfonylurea and metformin.

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.

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.

For the treatment of atopic dermatitis only if the following conditions are met;

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

Renewal Criteria
• The physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) six months after treatment initiation.
• The physician must provide proof of maintenance of EASI-75 response from baseline every six months for subsequent authorizations.
Prescribing Conditions
• The patient must be under the care of a dermatologist.
• Dupilumab is not to be used in combination with phototherapy or immunosuppressant drugs, such as methotrexate or cyclosporine.

SMOOTH MUSCLE RELAXANTS

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand</th>
<th>Active Ingredient</th>
<th>Strength</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>02275066</td>
<td>Trosec</td>
<td>trospium</td>
<td>20 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02488353</td>
<td>Mar-Trospium</td>
<td>trospium</td>
<td>20 mg</td>
<td>Tablet</td>
</tr>
</tbody>
</table>

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

MISCELLANEOUS THERAPEUTIC AGENTS

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand</th>
<th>Active Ingredient</th>
<th>Strength</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>02298384</td>
<td>Teva-Risedronate</td>
<td>risedronate</td>
<td>30 mg</td>
<td>Tablet</td>
</tr>
</tbody>
</table>

For the treatment of Paget's Disease.

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand</th>
<th>Active Ingredient</th>
<th>Strength</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>02343541</td>
<td>Prolia</td>
<td>denosumab</td>
<td>60 mg/mL</td>
<td>Injection</td>
</tr>
</tbody>
</table>

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;
- 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).
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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand Name</th>
<th>Active Ingredient</th>
<th>Strength</th>
<th>Formulation</th>
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</thead>
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<tr>
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<td>Injection</td>
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<td>Taro-Zoledronic Acid</td>
<td>zoledronic acid</td>
<td>5 mg/100 mL</td>
<td>Injection</td>
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<td>02422433</td>
<td>Zoledronic Acid</td>
<td>zoledronic acid</td>
<td>5 mg/100 mL</td>
<td>Injection</td>
</tr>
</tbody>
</table>

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).

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand Name</th>
<th>Active Ingredient</th>
<th>Strength</th>
<th>Formulation</th>
</tr>
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<tbody>
<tr>
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<td>Xgeva</td>
<td>denosumab</td>
<td>120 mg</td>
<td>Injection</td>
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</tbody>
</table>

(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.
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.*

Orencia
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.*
Avsola will be a preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Rheumatoid Arthritis, Ankylosing Spondylitis, Crohn’s Disease, Ulcerative Colitis, Psoriatic Arthritis, and Psoriasis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

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

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

**Avsola will be a preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Ankylosing Spondylitis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients. Patients will not be permitted to switch from Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.**

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

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

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

**For Pediatrics:** Avsola will be a preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Crohn’s Disease. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients. Patients will not be permitted to switch from Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.

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

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

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

**For Adults:** Avsola will be a preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Fistulizing Crohn’s Disease. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients. Patients will not be permitted to switch from Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.
Psoriasis
For the treatment of adult patients with severe plaque psoriasis with one or more of the following:
- Psoriasis Area and Severity Index (PASI) ≥10;
- Body Surface Area (BSA) > 10 percent;
- Dermatology Life Quality Index (DLQI) > 10;
- Significant involvement of the face, hands, feet or genital region; AND
- Failure to respond to, contraindications to, intolerant of or unable to access methotrexate, cyclosporine and/or phototherapy.

The initial request is approved for a maximum of 4 months. For continued coverage the physician must confirm the patient’s response to treatment and demonstration of treatment clinical benefits:
- ≥ 50 percent reduction in the PASI score with ≥ 5 point improvement in the DLQI; OR
- ≥ 75 percent reduction in the PASI score; OR
- ≥ 50 percent reduction in the BSA with significant improvement of the face, hands, feet or genital region.

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

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

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

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

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

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

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

Avsola will be a preferred infliximab option for all infliximab-naive patients prescribed an infliximab product for Rheumatoid Arthritis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients. Patients will not be permitted to switch from Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.
Ulcerative Colitis
For the treatment of patients with moderate to severely active ulcerative colitis who have had an inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

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

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

Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients. Patients will not be permitted to switch from Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.

| 02455323 | Brenzys | etanercept | 50 mg/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.

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

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

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

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

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

Brenzys will be a preferred etanercept option for all etanercept-naive patients weighing 63kg (138 pounds) or more who are prescribed an etanercept product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients.

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

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

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

Brenzys will be a preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Psoriatic Arthritis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients. Patients will not be permitted to switch from Brenzys to another etanercept product or vice versa, if previously trialed and deemed unresponsive to etanercept.
Rheumatoid Arthritis
For treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARD’s must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

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

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

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

Erelzi will be a preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Ankylosing Spondylitis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients. Patients will not be permitted to switch from Erelzi to another etanercept product or vice versa, if previously trialed and deemed unresponsive to etanercept.

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

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

Erelzi will be a preferred etanercept option for all etanercept-naive patients weighing 63kg (138 pounds) or more who are prescribed an etanercept product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients. Patients will not be permitted to switch from Erelzi to another etanercept product or vice versa, if previously trialed and deemed unresponsive to etanercept.
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.
Erelzi will be a preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Psoriasis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients. Patients will not be permitted to switch from Erelzi to another etanercept product or vice versa, if previously trialed and deemed unresponsive to etanercept.
Psoriatic Arthritis
For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARD’s must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.
Request for coverage must be made by a specialist in rheumatology.
Erelzi will be a preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Psoriatic Arthritis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients. Patients will not be permitted to switch from Erelzi to another etanercept product or vice versa, if previously trialed and deemed unresponsive to etanercept.
Rheumatoid Arthritis
For treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARD’s must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.
Request for coverage must be made by a specialist in rheumatology.

_Erelzi will be a preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Rheumatoid Arthritis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients._

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

| 02274728 | Enbrel | etanercept | 50 mg/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.

_Request for coverage must be made by a specialist in rheumatology._

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

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

**Psoriasis**

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

- Psoriasis Area and the Severity Index (PASI) ≥ 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._

_Erelzi or Brenzys will be the preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Psoriasis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients._

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

**Psoriatic Arthritis**

For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARD’s must also be tried.

Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

_Request for coverage must be made by a specialist in rheumatology._
Erelzi or Brenzys will be the preferred etanercept option for all etanercept-naive patients prescribed an etanercept product for Psoriatic Arthritis. Preferred means the first etanercept product to be considered for reimbursement for etanercept-naive patients.

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

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

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

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

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

| 02474263 | Humira | adalimumab | 20 mg/0.2 mL | Injection |

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

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

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

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

| 02258595 | Humira | adalimumab | 40 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.

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

- Previously trialed and deemed unresponsive to adalimumab.
Crohn’s Disease
For treatment of moderate to severely active Crohn’s Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.

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

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

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

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

Fistulizing Crohn’s Disease
For the treatment of Fistulizing Crohn’s Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:
• Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
• Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn's Disease. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Humira, Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

Hidradenitis Suppurativa
For the treatment of adult patients with active moderate to severe hidradenitis suppurativa who have not responded to conventional therapy (including systemic antibiotics) and who meet all of the following:
• A total abscess and nodule count of 3 or greater
• Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
• An inadequate response to a 90-day trial of oral antibiotics
• Prescribed by a practitioner with expertise in the management of patients with HS

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

Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Humira, Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yuflyma to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.
Polyarticular Juvenile Idiopathic Arthritis
For the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who are intolerant to or have inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).
Request for coverage must be made by a specialist in rheumatology.
Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yulfyma will be the preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis.
Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Humira, Abrilada, Amgevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi or Yulfyma to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

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

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.

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

• Previously trialed and deemed unresponsive to adalimumab.

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.

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

• Previously trialed and deemed unresponsive to adalimumab.

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.

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

• Previously trialed and deemed unresponsive to adalimumab.

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

- Previously trialed and deemed unresponsive to adalimumab.

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

Request for coverage must be made by a specialist in gastroenterology.
For Adults: Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.

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

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

- Previously trialed and deemed unresponsive to adalimumab.

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

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

Request for coverage must be made by a specialist in gastroenterology.
Abrisada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn's Disease.

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

- Previously trialed and deemed unresponsive to adalimumab.

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.

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

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

Request for coverage must be made by a specialist in rheumatology.
Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Abrilada to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

Psoriasis
For treatment of adult patients with severe plaque psoriasis presently with one or more of the following:
• Psoriasis Area and the Severity Index (PASI) ≥ 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.
Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriasis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Abrilada to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

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

Request for coverage must be made by a specialist in rheumatology.
Abrilada will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Abrilada to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.
Rheumatoid Arthritis
For treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

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

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

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

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

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

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

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

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

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

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

For Pediatrics: Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn’s Disease.
Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

**Fistulizing Crohn’s Disease**
For the treatment of Fistulizing Crohn’s Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:
• Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
• Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

Request for coverage must be made by a specialist in gastroenterology.
Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn’s Disease.
Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

**Hidradenitis Suppurativa**
For the treatment of adult patients with active moderate to severe hidradenitis suppurativa who have not responded to conventional therapy (including systemic antibiotics) and who meet all of the following:
• A total abscess and nodule count of 3 or greater
• Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
• An inadequate response to a 90-day trial of oral antibiotics
• Prescribed by a practitioner with expertise in the management of patients with HS

Note: Treatment with adalimumab should be discontinued if there is no improvement after 12 weeks of treatment.
Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

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

Request for coverage must be made by a specialist in rheumatology.
Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.
Psoriasis
For treatment of adult patients with severe plaque psoriasis presently with one or more of the following:
- Psoriasis Area and the Severity Index (PASI) \(\geq 10\)
- Body Surface Area (BSA) > 10%
- Significant involvement of the face, hands, feet or genital region
- Dermatology Life Quality Index (DLQI) > 10 AND
- Failure to respond to, contraindications to, intolerant of or unable to access methotrexate, cyclosporine and/or phototherapy.
Coverage will be approved initially for a maximum of 4 months. For continued coverage the physician must confirm the patient’s response to treatment and demonstration of treatment clinical benefits:
- \(\geq 50\%\) reduction in the PASI score with \(\geq 5\) point improvement in the DLQI
- \(\geq 75\%\) reduction in the PASI score
- \(\geq 50\%\) reduction in the BSA with significant improvement of the face, hands, feet or genital region.
*Request for coverage must be made by a specialist in dermatology.*
Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriasis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:
- Previously trialed and deemed unresponsive to adalimumab.

Psoriatic Arthritis
For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.
*Request for coverage must be made by a specialist in rheumatology.*
Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:
- Previously trialed and deemed unresponsive to adalimumab.
For treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.
*Request for coverage must be made by a specialist in rheumatology.*
Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Rheumatoid Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:
- Previously trialed and deemed unresponsive to adalimumab.
Ulcerative Colitis
For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.
Request for coverage must be made by a specialist in gastroenterology.
Amgevita will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Amgevita to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

Ankylosing Spondylitis
For the treatment of patients with active ankylosing spondylitis who have failed to respond to an adequate trial of at least three different nonsteroidal anti-inflammatory drugs (NSAIDs) and, in patients with peripheral joint involvement, who have failed to respond to methotrexate or sulfasalazine.
Request for coverage must be made by a specialist in rheumatology.
Hadlima will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hadlima to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

Crohn’s Disease
For treatment of moderate to severely active Crohn’s Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.
Request for coverage must be made by a specialist in gastroenterology.
For Adults: Hadlima will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn’s Disease.
Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hadlima to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

Fistulizing Crohn’s Disease
For the treatment of Fistulizing Crohn’s Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:
• Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
• Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).
Request for coverage must be made by a specialist in gastroenterology.
Hadlima will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn’s Disease.
Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hadlima to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

**Hidradenitis Suppurativa**
For the treatment of adult patients with active moderate to severe hidradenitis suppurativa who have not responded to conventional therapy (including systemic antibiotics) and who meet all of the following:
• A total abscess and nodule count of 3 or greater
• Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
• An inadequate response to a 90-day trial of oral antibiotics
• Prescribed by a practitioner with expertise in the management of patients with HS
Note: Treatment with adalimumab should be discontinued if there is no improvement after 12 weeks of treatment.

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

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

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

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

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

• Previously trialed and deemed unresponsive to adalimumab.

**Psoriatic Arthritis**

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

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

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

• Previously trialed and deemed unresponsive to adalimumab.

**Rheumatoid Arthritis**

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

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

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

• Previously trialed and deemed unresponsive to adalimumab.

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

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

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

• Previously trialed and deemed unresponsive to adalimumab.
Ankylosing Spondylitis
For the treatment of patients with active ankylosing spondylitis who have failed to respond to an adequate trial of at least three different nonsteroidal anti-inflammatory drugs (NSAIDs) and, in patients with peripheral joint involvement, who have failed to respond to methotrexate or sulfasalazine.
Request for coverage must be made by a specialist in rheumatology.
Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

Crohn's Disease
For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.
Request for coverage must be made by a specialist in gastroenterology.
For Adults: Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.
For Pediatrics: Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease.
Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

Fistulizing Crohn's Disease
For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:
• Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
• Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).
Request for coverage must be made by a specialist in gastroenterology.
Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn's Disease.
Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

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<td>40 mg/0.8 mL</td>
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</table>
Hidradenitis Suppurativa
For the treatment of adult patients with active moderate to severe hidradenitis suppurativa who have not responded to conventional therapy (including systemic antibiotics) and who meet all of the following:
• A total abscess and nodule count of 3 or greater
• Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
• An inadequate response to a 90-day trial of oral antibiotics
• Prescribed by a practitioner with expertise in the management of patients with HS
Note: Treatment with adalimumab should be discontinued if there is no improvement after 12 weeks of treatment.
Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

Polyarticular Juvenile Idiopathic Arthritis
For the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who are intolerant to or have inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).
Request for coverage must be made by a specialist in rheumatology.
Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

Psoriatic Arthritis
For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.
Request for coverage must be made by a specialist in rheumatology.
Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.
**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.*

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

**Rheumatoid Arthritis**
For treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented.

One combination therapy of DMARDs must also be tried.

Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

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

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

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

Hulio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hulio to another adalimumab product or vice versa, if:
- Previously trialed and deemed unresponsive to adalimumab.
Ankylosing Spondylitis
For the treatment of patients with active ankylosing spondylitis who have failed to respond to an adequate trial of at least three different nonsteroidal anti-inflammatory drugs (NSAIDs) and, in patients with peripheral joint involvement, who have failed to respond to methotrexate or sulfasalazine.

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

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

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

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

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

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

Fistulizing Crohn’s Disease
For the treatment of Fistulizing Crohn’s Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:
• Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
• Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

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

Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.
Hidradenitis Suppurativa
For the treatment of adult patients with active moderate to severe hidradenitis suppurativa who have not responded to conventional therapy (including systemic antibiotics) and who meet all of the following:
• A total abscess and nodule count of 3 or greater
• Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
• An inadequate response to a 90-day trial of oral antibiotics
• Prescribed by a practitioner with expertise in the management of patients with HS
Note: Treatment with adalimumab should be discontinued if there is no improvement after 12 weeks of treatment.
Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:
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Polyarticular Juvenile Idiopathic Arthritis
For the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who are intolerant to or have inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).
Request for coverage must be made by a specialist in rheumatology.
Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:
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Psoriatic Arthritis
For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.
Request for coverage must be made by a specialist in rheumatology.
Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:
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Psoriasis
For treatment of adult patients with severe plaque psoriasis presently with one or more of the following:
• Psoriasis Area and the Severity Index (PASI) ≥ 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.

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

**Rheumatoid Arthritis**

For treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented.

One combination therapy of DMARDs must also be tried.

Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

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

**Ulcerative Colitis**

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

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

Hyrimoz will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Hyrimoz to another adalimumab product or vice versa, if:
- Previously trialed and deemed unresponsive to adalimumab.
Ankylosing Spondylitis
For the treatment of patients with active ankylosing spondylitis who have failed to respond to an adequate trial of at least three different nonsteroidal anti-inflammatory drugs (NSAIDs) and, in patients with peripheral joint involvement, who have failed to respond to methotrexate or sulfasalazine.
*Request for coverage must be made by a specialist in rheumatology.*
Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:
*• Previously trialed and deemed unresponsive to adalimumab.*

Crohn’s Disease
For treatment of moderate to severely active Crohn’s Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.
*Request for coverage must be made by a specialist in gastroenterology.*
For Adults: Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn’s Disease.
For Pediatrics: Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn’s Disease.
Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:
*• Previously trialed and deemed unresponsive to adalimumab.*

Fistulizing Crohn’s Disease
For the treatment of Fistulizing Crohn’s Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:
• Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
• Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).
*Request for coverage must be made by a specialist in gastroenterology.*
Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Fistulizing Crohn’s Disease.
Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:
*• Previously trialed and deemed unresponsive to adalimumab.*
Hidradenitis Suppurativa
For the treatment of adult patients with active moderate to severe hidradenitis suppurativa who have not responded to conventional therapy (including systemic antibiotics) and who meet all of the following:
• A total abscess and nodule count of 3 or greater
• Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
• An inadequate response to a 90-day trial of oral antibiotics
• Prescribed by a practitioner with expertise in the management of patients with HS
Note: Treatment with adalimumab should be discontinued if there is no improvement after 12 weeks of treatment.
Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:
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Polyarticular Juvenile Idiopathic Arthritis
For the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who are intolerant to or have inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).
Request for coverage must be made by a specialist in rheumatology.
Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

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.
Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriasis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:
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**Psoriatic Arthritis**
For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:
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**Rheumatoid Arthritis**
For treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Rheumatoid Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:
* Previously trialed and deemed unresponsive to adalimumab.
Ulcerative Colitis
For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.
Request for coverage must be made by a specialist in gastroenterology.
Idacio will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Idacio to another adalimumab product or vice versa, if:
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Ankylosing Spondylitis
For the treatment of patients with active ankylosing spondylitis who have failed to respond to an adequate trial of at least three different nonsteroidal anti-inflammatory drugs (NSAIDs) and, in patients with peripheral joint involvement, who have failed to respond to methotrexate or sulfasalazine.
Request for coverage must be made by a specialist in rheumatology.
Simlandi will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ankylosing Spondylitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Simlandi to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

Crohn's Disease
For treatment of moderate to severely active Crohn's Disease in patients with inadequate response, intolerance or contraindications to an adequate course of corticosteroids AND an immunosuppressive agent.
Request for coverage must be made by a specialist in gastroenterology.
For Adults: Simlandi will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Crohn's Disease. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Simlandi to another adalimumab product or vice versa, if:
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**Fistulizing Crohn’s Disease**
For the treatment of Fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:

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

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

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

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

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

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

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

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

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

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

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

- Previously trialed and deemed unresponsive to adalimumab.
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.
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Psoriatic Arthritis
For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.
Request for coverage must be made by a specialist in rheumatology.
Simlandi will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Simlandi to another adalimumab product or vice versa, if:
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Request for coverage must be made by a specialist in rheumatology.
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For the treatment of patients over 18 years of age with moderate to severely active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

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

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

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

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

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

• Previously trialed and deemed unresponsive to adalimumab.

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

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

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

• Previously trialed and deemed unresponsive to adalimumab.

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

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

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

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

• Previously trialed and deemed unresponsive to adalimumab.
Hidradenitis Suppurativa
For the treatment of adult patients with active moderate to severe hidradenitis suppurativa who have not responded to conventional therapy (including systemic antibiotics) and who meet all of the following:
• A total abscess and nodule count of 3 or greater
• Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
• An inadequate response to a 90-day trial of oral antibiotics
• Prescribed by a practitioner with expertise in the management of patients with HS
Note: Treatment with adalimumab should be discontinued if there is no improvement after 12 weeks of treatment.
Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Hidradenitis Suppurativa. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

Polyarticular Juvenile Idiopathic Arthritis
For the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who are intolerant to or have inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).
Request for coverage must be made by a specialist in rheumatology.
Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Polyarticular Juvenile Idiopathic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

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.
Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriasis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naïve patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.
Psoriatic Arthritis
For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

Request for coverage must be made by a specialist in rheumatology.
Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Psoriatic Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

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

Request for coverage must be made by a specialist in rheumatology.
Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Rheumatoid Arthritis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

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

Request for coverage must be made by a specialist in gastroenterology.
Yuflyma will be a preferred adalimumab option for all adalimumab-naïve patients prescribed an adalimumab product for Ulcerative Colitis. Preferred means the first adalimumab product to be considered for reimbursement for adalimumab-naive patients. Patients will not be permitted to switch from Yuflyma to another adalimumab product or vice versa, if:
• Previously trialed and deemed unresponsive to adalimumab.

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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.

Updated: June 22, 2023
### 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.*

### 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 sulfazalazine.

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

*Renflexis will be a preferred infliximab option for all infliximab-naive patients who have been prescribed an infliximab product for Ankylosing Spondylitis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients. Patients will not be permitted to switch from Renflexis to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.*

**Crohn’s Disease**

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

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

*For Adults: Renflexis will be a preferred infliximab option for all infliximab-naive adult patients prescribed an infliximab product for Crohn's Disease. For Pediatrics: Renflexis will be a preferred infliximab option for all infliximab-naive pediatric patients prescribed an infliximab product for Crohn's Disease. Preferred means the firstfliximab product to be considered for reimbursement for infliximab-naive patients. Patients will not be permitted to switch from Renflexis to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.*
**Fistulizing Crohn’s Disease**
For the treatment of Fistulizing Crohn’s Disease in patients with actively draining perianal or enterocutaneous fistula who meet the following criteria:
- Presence of fistula that has persisted despite a course of antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND
- Have had inadequate response, intolerance or contraindications to an immunosuppressive agent (e.g. azathioprine or 6 mercaptopurine).

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

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

*Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.*

*Patients will not be permitted to switch from Renflexis to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.*

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

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

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

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

*Patients will not be permitted to switch from Renflexis to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.*
Psoriatic Arthritis
For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindication to these agents is documented. One combination therapy of DMARD must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

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

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

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

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

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

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

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

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

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

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

Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

Patients will not be permitted to switch from Renflexis to another infliximab product or vice versa, if previously trialed and deemed unresponsive to infliximab.
**Ankylosing Spondylitis**

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

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

*Inflectra will be a preferred infliximab option for all infliximab-naïve patients prescribed an infliximab product for Ankylosing Spondylitis. Preferred means the first infliximab product to be considered for reimbursement for infliximab-naïve patients.*

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

**Crohn’s Disease**

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

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

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

*For Pediatrics: Inflectra will be a preferred infliximab option for all infliximab-naïve pediatric patients prescribed an infliximab product for Crohn’s Disease.*

*Preferred means the first infliximab product to be considered for reimbursement for infliximab-naïve patients.*

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

**Fistulizing Crohn’s Disease**

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

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

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

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

*For Pediatrics: Inflectra will be a preferred infliximab option for all infliximab-naïve pediatric patients prescribed an infliximab product for Fistulizing Crohn’s Disease.*

*Preferred means the first infliximab product to be considered for reimbursement for infliximab-naïve patients.*

*Patients will not be permitted to switch from Inflectra to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.*
Psoriasis
For the treatment of adult patients with severe plaque psoriasis with one or more of the following:
- Psoriasis Area and Severity Index (PASI) ≥ 10;
- Body Surface Area (BSA) > 10 percent;
- Dermatology Life Quality Index (DLQI) > 10;
- Significant involvement of the face, hands, feet or genital region; AND
- Failure to respond to, contraindications to, intolerant of or unable to access methotrexate, cyclosporine and/or phototherapy.

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

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

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

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

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

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

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

Patients will not be permitted to switch from Inflectra to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.
Rheumatoid Arthritis
For the treatment of patients over 18 years of age who have moderate to severe active rheumatoid arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

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

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

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

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

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

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

Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

*Patients will not be permitted to switch from Inflectra to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.*
Ankylosing Spondylitis
For the treatment of patients with active ankylosing spondylitis who have failed to respond to an adequate trial of at least three different non-steroidal anti-inflammatory drugs (NSAIDs) and, in patients with peripheral joint involvement, have failed to respond to methotrexate or sulfasalazine.

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

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

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

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

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

For Pediatrics: Renflexis, Inflectra or Avsola will be the preferred infliximab option for all infliximab-naive pediatric patients prescribed an infliximab product for Crohn’s Disease.

Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.

Patients will not be permitted to switch from Remicade, Renflexis, Inflectra or Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.
**Fistulizing Crohn’s Disease**

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

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

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

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

For Pediatrics: Renflexis, Inflectra or Avsola will be the preferred infliximab option for all infliximab-naive pediatric patients prescribed an infliximab product for Fistulizing Crohn’s Disease.

Preferred means the first infliximab product to be considered for reimbursement for infliximab-naïve patients.

Patients will not be permitted to switch from Remicade, Renflexis, Inflectra or Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.

**Psoriasis**

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

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

The initial request is approved for a maximum of 4 months. For continued coverage the physician must confirm the patient’s response to treatment and demonstration of treatment clinical benefits:

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

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

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

Patients will not be permitted to switch from Remicade, Renflexis, Inflectra or Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.
Psoriatic Arthritis
For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindication to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

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

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

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

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

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

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

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

For Pediatrics: Renflexis, Inflectra or Avsola will be the preferred infliximab option for all infliximab-naive pediatric patients prescribed an infliximab product for Ulcerative Colitis.

Preferred means the first infliximab product to be considered for reimbursement for infliximab-naive patients.
Patients will not be permitted to switch from Remicade, Renflexis, Inflectra or Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.
For the treatment of severely active rheumatoid arthritis (RA), in combination with methotrexate, for patients who have failed to respond to an adequate trial of one or more anti-tumor necrosis factor (anti-TNF) agents (monoclonal antibody OR fusion protein) OR who are contraindicated to anti-TNF agents.

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

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

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

Rheumatoid Arthritis

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

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

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

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

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

Riabni, Riximyo, Ruxience or Truxima will be the preferred rituximab option for all rituximab-naive patients prescribed a rituximab product for GPA and MPA. Preferred means the first rituximab product to be considered for reimbursement for rituximab-naive patients. Patients will not be permitted to switch from Riabni, Rituxan, Riximyo, Ruxience or Truxima to another rituximab product or vice versa, if previously trialed and deemed unresponsive to therapy.
### Rheumatoid Arthritis
For the treatment of severely active rheumatoid arthritis (RA), in combination with methotrexate, for patients who have failed to respond to an adequate trial of one or more anti-tumor necrosis factor (anti-TNF) agents (monoclonal antibody OR fusion protein) OR who are contraindicated to anti-TNF agents.

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

*Riximyo will be a preferred rituximab option for all rituximab-naive patients prescribed a rituximab product for Rheumatoid Arthritis. Preferred means the first rituximab product to be considered for reimbursement for rituximab-naive patients.*

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

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

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

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

*Riximyo will be a preferred rituximab option for all rituximab-naive patients prescribed a rituximab product for GPA and MPA. Preferred means the first rituximab product to be considered for reimbursement for rituximab-naive patients.*

*Patients will not be permitted to switch from Riximyo to another rituximab product or vice versa, if previously trialed and deemed unresponsive to therapy.*
Rheumatoid Arthritis
For the treatment of severely active rheumatoid arthritis (RA), in combination with methotrexate, for patients who have failed to respond to an adequate trial of one or more anti-tumor necrosis factor (anti-TNF) agents (monoclonal antibody OR fusion protein) OR who are contraindicated to anti-TNF agents.

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

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

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

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

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.

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.

<table>
<thead>
<tr>
<th>Actemra</th>
<th>tocilizumab</th>
<th>80 mg/4 mL</th>
<th>200 mg/10 mL</th>
<th>400 mg/20 mL</th>
<th>Injection</th>
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</thead>
</table>

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.
Simponi  
golimumab  
Injection

50 mcg/0.5 mL
50 mcg/0.5 mL
100 mg/1 mL
100 mg/1 mL

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 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.

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.

Simponi IV  
golimumab  
Injection

50 mg/4 mL

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

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

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.
### 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.*

### 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.*

### Psoriasis

For treatment of adult patients with severe plaque psoriasis presently with one or more of the following:
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- Body Surface Area (BSA) > 10%
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- ≥ 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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Strength</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>02525267</td>
<td>Bimzelx</td>
<td>bimekizumab 160 mg/mL</td>
<td>Prefilled Syringe</td>
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<tr>
<td>02525275</td>
<td>Bimzelx</td>
<td>bimekizumab 160 mg/mL</td>
<td>Autoinjector</td>
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</table>

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- Psoriasis Area and the Severity Index (PASI) ≥ 10
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- ≥ 75% reduction in the PASI score
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Request for coverage must be made by a specialist in dermatology.

<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Strength</th>
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<tr>
<td>02473623</td>
<td>Siliq</td>
<td>brodalumab 210 mg/1.5 mL</td>
<td>Injection</td>
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</tbody>
</table>

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- ≥ 75% reduction in the PASI score
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<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Formulation</th>
<th>Dosage</th>
<th>Form</th>
<th>Brand</th>
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<tr>
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<td>risankizumab</td>
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<td>risankizumab</td>
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<table>
<thead>
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<th>Code</th>
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<td>02269201</td>
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<td>02505762</td>
<td>Apo-Dimethyl Fumarate</td>
<td>dimethyl fumarate</td>
<td>120 mg</td>
<td>Capsule</td>
<td></td>
</tr>
<tr>
<td>02505770</td>
<td></td>
<td></td>
<td>240 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>02494809</td>
<td>GLN-Dimethyl Fumarate</td>
<td>dimethyl fumarate</td>
<td>120 mg</td>
<td>Capsule</td>
<td></td>
</tr>
<tr>
<td>02494817</td>
<td></td>
<td></td>
<td>240 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>02516047</td>
<td>Jamp Dimethyl Fumarate</td>
<td>dimethyl fumarate</td>
<td>120 mg</td>
<td>Capsule</td>
<td></td>
</tr>
<tr>
<td>02516055</td>
<td></td>
<td></td>
<td>240 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>02502690</td>
<td>Mar-Dimethyl Fumarate</td>
<td>dimethyl fumarate</td>
<td>120 mg</td>
<td>Capsule</td>
<td></td>
</tr>
<tr>
<td>02502704</td>
<td></td>
<td></td>
<td>240 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>02497026</td>
<td>pms-Dimethyl Fumarate</td>
<td>dimethyl fumarate</td>
<td>120 mg</td>
<td>Capsule</td>
<td></td>
</tr>
<tr>
<td>02497034</td>
<td></td>
<td></td>
<td>240 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>02513781</td>
<td>Sandoz Dimethyl Fumarate</td>
<td>dimethyl fumarate</td>
<td>120 mg</td>
<td>Capsule</td>
<td></td>
</tr>
<tr>
<td>02513803</td>
<td></td>
<td></td>
<td>240 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>02286386</td>
<td>Tysabri</td>
<td>natalizumab</td>
<td>300 mg/15 mL</td>
<td>Injection</td>
<td></td>
</tr>
</tbody>
</table>

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

*Glatect will be a preferred glatiramer acetate option for all glatiramer acetate-naive patients prescribed a glatiramer acetate product for relapsing-remitting multiple sclerosis (MS). Patients will not be permitted to switch from Glatect to another glatiramer acetate product or vice versa, if previously trialed and deemed unresponsive to therapy.*
<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Active Ingredient(s)</th>
<th>Dosage</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>02511355</td>
<td>Kesimpta</td>
<td>ofatumumab</td>
<td>20 mg/0.4 mL</td>
<td>Injection</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kesimpta</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>olaftumumab</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02470179</td>
<td>Mavenclad</td>
<td>cladribine</td>
<td>10 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02244550</td>
<td>Pamidronate Disodium</td>
<td>pamidronate disodium</td>
<td>3 mg/mL</td>
<td>Injection</td>
</tr>
<tr>
<td>02244555</td>
<td>Pamidronate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Disodium</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02245665</td>
<td>Pamidronate Disodium Omega</td>
<td>pamidronat+A1698:C1721 edisodium</td>
<td>9 mg/mL</td>
<td>Injection</td>
</tr>
<tr>
<td></td>
<td>Patients unable to absorb oral medications due to Crohn's Disease or other absorption problems (use for the treatment of osteoporosis).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02296462</td>
<td>Advagraf</td>
<td>tacrolimus</td>
<td>0.5 mg</td>
<td>Capsule</td>
</tr>
<tr>
<td>02296470</td>
<td></td>
<td></td>
<td>1 mg</td>
<td></td>
</tr>
<tr>
<td>0231667</td>
<td></td>
<td></td>
<td>3 mg</td>
<td></td>
</tr>
<tr>
<td>02296489</td>
<td></td>
<td></td>
<td>5 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>For the prophylaxis of organ rejection in patients receiving allogeneic liver or kidney transplants.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02485877</td>
<td>Envarsus PA</td>
<td>tacrolimus</td>
<td>0.75 mg</td>
<td>Extended Release Tablet</td>
</tr>
<tr>
<td>02485885</td>
<td></td>
<td></td>
<td>1 mg</td>
<td></td>
</tr>
<tr>
<td>02485893</td>
<td></td>
<td></td>
<td>4 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>For the prophylaxis of organ rejection in patients receiving allogeneic liver or kidney transplants.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02243144</td>
<td>Prograf</td>
<td>tacrolimus</td>
<td>0.5 mg</td>
<td>Capsule</td>
</tr>
<tr>
<td>02175991</td>
<td></td>
<td></td>
<td>1 mg</td>
<td></td>
</tr>
<tr>
<td>02175983</td>
<td></td>
<td></td>
<td>5 mg</td>
<td></td>
</tr>
<tr>
<td>02176009</td>
<td>Prograf</td>
<td>tacrolimus</td>
<td>5 mg/mL</td>
<td>Injection</td>
</tr>
<tr>
<td>00960632</td>
<td>Prograf</td>
<td>tacrolimus</td>
<td>0.5 mg/mL</td>
<td>Suspension</td>
</tr>
<tr>
<td>02416816</td>
<td>Sandoz Tacrolimus</td>
<td>tacrolimus</td>
<td>0.5 mg</td>
<td>Capsule</td>
</tr>
<tr>
<td>02416824</td>
<td></td>
<td></td>
<td>1 mg</td>
<td></td>
</tr>
<tr>
<td>02416832</td>
<td></td>
<td></td>
<td>5 mg</td>
<td></td>
</tr>
</tbody>
</table>

(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.
<table>
<thead>
<tr>
<th>Code</th>
<th>Brand</th>
<th>Active Ingredient</th>
<th>Strength(s)</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>02264560</td>
<td>Myfortic</td>
<td>mycophenolate sodium</td>
<td>180 mg 360 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02264579</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02372738</td>
<td>Apo-Mycophenolic Acid</td>
<td>mycophenolate sodium</td>
<td>180 mg 360 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02372746</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02511673</td>
<td>Mar-Mycophenolic Acid</td>
<td>mycophenolic sodium</td>
<td>180 mg 360 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02511681</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand</th>
<th>Active Ingredient</th>
<th>Strength(s)</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>00718149</td>
<td>Tryptan</td>
<td>L-tryptophan</td>
<td>500 mg 1 g</td>
<td>Capsule</td>
</tr>
<tr>
<td>02029456</td>
<td>Tryptan</td>
<td>L-tryptophan</td>
<td>500 mg 1 g</td>
<td>Tablet</td>
</tr>
<tr>
<td>00654531</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02248540</td>
<td>Apo-Tryptophan</td>
<td>L-tryptophan</td>
<td>500 mg 1 g</td>
<td>Capsule</td>
</tr>
<tr>
<td>02248538</td>
<td>Apo-Tryptophan</td>
<td>L-tryptophan</td>
<td>500 mg 750 mg 1 g</td>
<td>Tablet</td>
</tr>
<tr>
<td>02248539</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>02240334</td>
<td>TEVA-Tryptophan</td>
<td>L-tryptophan</td>
<td>500 mg 1 g</td>
<td>Capsule</td>
</tr>
<tr>
<td>02240333</td>
<td>TEVA-Tryptophan</td>
<td>L-tryptophan</td>
<td>500 mg 1 g</td>
<td>Tablet</td>
</tr>
<tr>
<td>02237250</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand</th>
<th>Active Ingredient</th>
<th>Strength(s)</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>02241888</td>
<td>Arava</td>
<td>leflunomide</td>
<td>10 mg 20 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02241889</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02478862</td>
<td>Accel-Leflunomide</td>
<td>leflunomide</td>
<td>10 mg 20 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02478870</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02256495</td>
<td>Apo-Leflunomide</td>
<td>leflunomide</td>
<td>10 mg 20 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02256509</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02351668</td>
<td>Leflunomide</td>
<td>leflunomide</td>
<td>10 mg 20 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02351676</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02261251</td>
<td>Teva-Leflunomide</td>
<td>leflunomide</td>
<td>10 mg 20 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02261278</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02283964</td>
<td>Sandoz Leflunomide</td>
<td>leflunomide</td>
<td>10 mg 20 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02283972</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Rheumatoid arthritis failing at least 2 disease modifying antirheumatic drugs (DMARDs), eg. gold, methotrexate (MTX), plaquenil, sulfasalazine, minocycline and doxycycline.
<table>
<thead>
<tr>
<th>Code</th>
<th>Product Name</th>
<th>Active Ingredients</th>
<th>Strength</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>02233542</td>
<td>Diane-35</td>
<td>cyproterone acetate/ethinyl estradiol</td>
<td>2 mg/0.035 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02290308</td>
<td>Cyestra-35</td>
<td>cyproterone acetate/ethinyl estradiol</td>
<td>2 mg/0.035 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02309556</td>
<td>Novo-Cyproterone/Ethinyl Estradiol</td>
<td>cyproterone acetate/ethinyl estradiol</td>
<td>2 mg/0.035 mg</td>
<td>Tablet</td>
</tr>
</tbody>
</table>

(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).

<table>
<thead>
<tr>
<th>Code</th>
<th>Product Name</th>
<th>Strength</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>01968017</td>
<td>Neupogen</td>
<td>300 mcg/mL, 300 mcg/0.5 mL, 480 mcg/0.8 mL</td>
<td>Injection</td>
</tr>
<tr>
<td>02420104</td>
<td>Grastofil</td>
<td>300 mcg/0.5 mL, 480 mcg/0.8 mL</td>
<td>Injection</td>
</tr>
<tr>
<td>02420112</td>
<td>Nivestym</td>
<td>300 mcg/mL, 480 mcg/1.6 mL, 300 mcg/0.5 mL, 480 mcg/0.8 mL</td>
<td>Injection</td>
</tr>
</tbody>
</table>

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

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

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

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

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

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

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.
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.

For the management of pediatric chronic inflammatory arthropathies.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Active Ingredient</th>
<th>Dosage</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>02242471</td>
<td>Dostinex</td>
<td>cabergoline</td>
<td>0.5 mg</td>
<td>Tablet</td>
</tr>
<tr>
<td>02455897</td>
<td>Apo-Cabergoline</td>
<td>cabergoline</td>
<td>0.5 mg</td>
<td>Tablet</td>
</tr>
</tbody>
</table>

For treatment of:

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Active Ingredient</th>
<th>Dosage</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>02473232</td>
<td>Fasenra</td>
<td>benralizumab</td>
<td>30 mg/mL</td>
<td>Injection</td>
</tr>
</tbody>
</table>

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 within the past 12 months AND has experienced two or more clinically significant asthma exacerbations in the past 12 months, or
   3.2. blood eosinophil count of ≥ 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.

Updated: June 22, 2023