Ontario

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – March 2021

Effective March 29, 2021

Drug Programs Policy and Strategy Branch

Drugs and Devices Division

Ministry of Health

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New Single Source Products

Generic Name: ADALIMUMAB

DIN/PIN	Brand Name	Strength	Dosage Form*	Mfr	DBP	LU Code
02459310	Amgevita	20mg/0.4mL	Inj Sol-0.4mL Pref Syr	AMG	235.6400 /Pref Syr	600 to 607, 609, 611
02459302	Amgevita	40mg/0.8mL	Inj Sol-0.8mL Pref Autoinj	AMG	471.2700 /Pref Autoinj	600 to 607, 609, 611
02459299	Amgevita	40mg/0.8mL	Inj Sol-0.8mL Pref Syr	AMG	471.2700 /Pref Syr	600 to 607, 609, 611
02502402	Hulio	40mg/0.8mL	Inj Sol-0.8mL Pref Pen	BGP	471.2700 /Pref Pen	600 to 607, 609, 611
02502399	Hulio	40mg/0.8mL	Inj Sol-0.8mL Pref Syr	BGP	471.2700 /Pref Syr	600 to 607, 609, 611
02502674	Idacio	40mg/0.8mL	Inj Sol-0.8mL Pref Pen	FKC	471.2700 /Pref Pen	600 to 607 609, 611
02473097	Hadlima	40mg/0.8mL	Inj Sol-0.8mL Pref Syr	SAM	471.2700 /Pref Syr	600 to 607, 609, 611
02473100	Hadlima PushTouch	40mg/0.8mL	Inj Sol-0.8mL Pref Autoinj	SAM	471.2700 /Pref Autoinj	600 to 607, 609, 611
02505258	Hyrimoz	20mg/0.4mL	Inj Sol-0.4mL Pref Syr	SDZ	235.6350 /Pref Syr	600 to 606, 608, 609, 612
02492156	Hyrimoz	40mg/0.8mL	Inj Sol-0.8mL Pref Autoinj	SDZ	471.2700 /Pref Autoinj	600 to 606, 608, 609, 612
02492164	Hyrimoz	40mg/0.8mL	Inj Sol-0.8mL Pref Syr	SDZ	471.2700 /Pref Syr	600 to 606, 608, 609, 612

*All formulations are preservative-free.

Reason for Use Code and Clinical Criteria

Code 600 (Rheumatoid Arthritis)

For the treatment of rheumatoid arthritis (RA) in patients who have severe active disease (greater than or equal to 5 swollen joints and rheumatoid factor positive and/or, anti-CCP positive, and/or radiographic evidence of rheumatoid arthritis) and have experienced failure, intolerance, or have a contraindication to adequate trials of disease-modifying anti-rheumatic drugs (DMARDs) treatment regimens, such as one of the following combinations of treatments:

A. i) Methotrexate (20mg/week) for at least 3 months, AND
ii) leflunomide (20mg/day) for at least 3 months, in addition to
iii) an adequate trial of at least one combination of DMARDs for 3 months; OR

B. i) Methotrexate (20mg/week) for at least 3 months, AND
ii) leflunomide in combination with methotrexate for at least 3 months; OR

C. i) Methotrexate (20mg/week), sulfasalazine (2g/day) and hydroxychloroquine (400mg/day) for at least 3 months. (Hydroxychloroquine is based by weight up to 400mg per day.)

Maintenance/Renewal:

After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 20 percent reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year.

For renewals beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

Therapy must be prescribed by a rheumatologist or a physician with expertise in rheumatology.

Approvals will only allow for standard dosing for adalimumab.

The recommended dosing regimen is 40mg every two weeks.

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 601 (Polyarticular Juvenile Idiopathic Arthritis)

For the treatment of polyarticular juvenile idiopathic arthritis (pJIA) in patients who have active disease (greater than or equal to 3 swollen joints and greater than or equal to 5 active joints) despite a trial of optimal doses of subcutaneously administered methotrexate (i.e. 15mg/m2 per week) for at least 3 months. If the patient is unable to tolerate or has a contraindication to subcutaneous methotrexate, the nature of the intolerance or contraindication should be documented.

Maintenance/Renewal:

After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 20 percent reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. For funding beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

Therapy must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

The recommended dosing regimen is for pediatric patients 2 years of age and older:

- 10kg to less than 30kg: 20mg every other week*
- 30kg and greater: 40mg every other week

* a dose of 10mg every other week can be considered for patients weighing 10kg to less than 15kg

It should be noted that some adalimumab products may not be available as 20mg injectables.

Prescribers should be informed and stay current with a drug's official Health Canada approved product monograph including available dosage formats.

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 602 (Psoriatic Arthritis)

For the treatment of psoriatic arthritis in patients who have severe active disease (greater than or equal to 5 swollen joints and radiographic evidence of psoriatic arthritis) despite: i) treatment with methotrexate (20mg/week) for at least 3 months; AND ii) one of leflunomide (20mg/day) or sulfasalazine (1g twice daily) for at least 3 months.

If the patient has documented contraindications or intolerances to methotrexate, then only one of leflunomide (20mg/day) or sulfasalazine (1g twice daily) for at least 3 months is required.

Maintenance/Renewal:

After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 20 percent reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. For funding beyond the second year, the patient must have objective evidence of preservation of treatment effect.

Therapy must be prescribed by a rheumatologist or a physician with expertise in rheumatology.

The recommended dosing regimen is 40mg every 2 weeks.

Higher doses may be considered case-by-case through the Exceptional Access Program.

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 603 (Ankylosing Spondylitis)

For the treatment of ankylosing spondylitis (AS) in patients who have severe active disease confirmed by radiographic evidence (see note below) with:

- Age of disease onset equal to or younger than 50; AND

- Low back pain and stiffness for greater than 3 months that improves with exercise and not relieved by rest; AND

- Failure to respond to or documented intolerance to adequate trials of 2 non-steroidal anti-inflammatory drugs (NSAIDs) for at least 4 weeks each; AND

- Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of greater than or equal to 4 for at least 4 weeks while on standard therapy.

NOTE: Radiographic evidence demonstrating the presence of "SI joint fusion" or "SI joint erosion" on x-ray or CT scan, or MRI demonstrating the presence of "inflammation" or "edema" of the SI joint.

Maintenance/Renewal:

After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 50 percent reduction in BASDAI score or greater than or equal to 2 absolute point reduction in BASDAI score. For funding beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

Therapy must be prescribed by a rheumatologist or a physician with expertise in rheumatology.

The recommended dosing regimen is 40mg every 2 weeks.

Higher doses may be considered case-by-case through the Exceptional Access Program.

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 604 (Crohn's Disease, Moderate to Severe)

For the treatment of moderate to severe (luminal) Crohn's Disease in patients who meet the following criteria:

A. Harvey Bradshaw Index (HBI) score greater than or equal to 7; AND

B. Failed to respond to conventional treatment with a corticosteroid equivalent to a daily dose of prednisone 40mg daily for at least 2 weeks OR the patient is stabilized on corticosteroid but cannot be tapered to a corticosteroid dose below prednisone 20mg daily or equivalent; AND

C. Failed to respond to an immunosuppressive agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) tried for at least 3 months (or where the use of immunosuppressants is contraindicated).

Approvals will only allow for standard dosing for adalimumab.

The recommended dosing regimen is 160mg at week 0; 80mg at week 2; followed by 40mg every two weeks.

Maintenance/Renewal:

Maintenance therapy is funded for patients who meet the Ministry initiation criteria and whose disease is maintained with a 50% reduction in the HBI from pre-treatment measurement, AND improvement of symptoms (e.g. absence of bloody diarrhea, weight is stable or increased), AND no longer using corticosteroids.

For continued funding beyond the first year, the patient must continue to demonstrate benefit and if unable to be discontinued on corticosteroids, the physician may wish to consider other funded alternatives.

Approvals will only allow for standard dosing for adalimumab.

The recommended dosing regimen is 40mg every 2 weeks.

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 605 (Crohn's Disease, Fistulising)

For the treatment of fistulising Crohn's disease with concomitant luminal disease in patients who meet the following criteria:

A. Patient has actively draining perianal or enterocutaneous fistula(e) that have recurred OR persist despite a course of appropriate antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) and immunosuppressive therapy (e.g. azathioprine or 6-mercaptopurine); AND

B. Harvey Bradshaw Index (HBI) score greater than or equal to 7

Approvals will only allow for standard dosing for adalimumab.

The recommended dosing regimen for induction is 160mg at week 0, followed by 80mg at week 2, then 40mg every other week.

Maintenance/Renewal:

Maintenance therapy is funded for patients who meet the Ministry initiation criteria and achieve and maintain response to therapy.

Approvals will only allow for standard dosing for adalimumab.

The recommended dosing regimen is 40mg every other week.

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 606 (Ulcerative Colitis)

For the treatment of ulcerative colitis disease in patients who meet the following criteria:

1. Moderate disease

   A. Mayo score between 6 and 10 (inclusive); AND

   B. Endoscopic* subscore of 2; AND

   C. Failed 2 weeks of oral prednisone at daily doses greater than or equal to 40mg (or a 1 week course of IV equivalent) and 3 months of azathioprine (AZA)/6-mercatopurine (6-MP) (or where the use of immunosuppressants is contraindicated);

   OR

   Stabilized with 2 weeks of oral prednisone at daily doses greater than or equal to 40mg (or 1 week of IV equivalent) but the corticosteroid dose cannot be tapered despite 3 months of AZA/6MP (or where the use of immunosuppressants is contraindicated).

2. Severe disease

   A. Mayo score greater than 10; AND

   B. Endoscopy* subscore of greater than or equal to 2; AND

   C. Failed 2 weeks of oral prednisone at daily doses greater than or equal to 40mg (or 1 week of IV equivalent)

   OR

   Stabilized with 2 weeks oral prednisone at daily doses greater than or equal to 40mg (or 1 week of IV equivalent) but demonstrated that the corticosteroid dose cannot be tapered despite 3 months of AZA/6MP (or where the use of immunosuppressants is contraindicated).

*The endoscopy procedure must be done within the 12 months prior to initiation of treatment.

Approvals will only allow for standard dosing for adalimumab.

The recommended dosing regimen for induction is 160mg at week 0, followed by 80mg at week 2, then 40mg every other week.

Maintenance/Renewal:

Maintenance therapy is funded for patients who meet the Ministry initiation criteria and whose disease is maintained at Mayo score less than 6 AND who demonstrate at least 50% reduction in the dose of prednisone compared with the starting dose following the first 6 months of treatment with adalimumab or be off corticosteroids after the first year of treatment.

Approvals will only allow for standard dosing for adalimumab.

The recommended dosing regimen is 40mg every other week.

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 607 (Hidradenitis Suppurativa – Adult and adolescent)

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

A. A total abscess and nodule count of 3 or greater; AND
B. Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III; AND
C. Experienced an inadequate response to a 90-day trial of oral antibiotics.

Therapy must be prescribed by a practitioner with expertise in the management of patients with HS.

The recommended adult dosing regimen is 160mg at week 0, followed by 80mg at week 2, then 40mg at week 4, and 40mg weekly thereafter.

The recommended adolescent dosing regimen is 80mg at week 0 followed by 40mg every other week starting at week 1 up to 40mg weekly in those with inadequate response.

If there is no improvement after 12 weeks of treatment with adalimumab at the Health Canada approved dose, higher doses are not recommended and the prescriber should discontinue treatment.

Prescribers should be informed and stay current with a drug's official Health Canada approved product monograph including available dosage formats.

Maintenance/Renewal:

Maintenance therapy is funded for patients beyond the first 12 weeks in those who meet the Ministry initiation criteria and who have responded to treatment defined as at least a 50% reduction in abscesses and inflammatory nodule count with no increase in abscess count or draining fistula count relative to baseline.

Maintenance therapy beyond the second year is funded for patients using adalimumab for HS, where there is objective evidence of the preservation of treatment effect (i.e. the current abscess and inflammatory nodule count should be compared to the count prior to initiating treatment with adalimumab).

The recommended maintenance dose is 40mg weekly.

Prescribers should be informed and stay current with a drug's official Health Canada approved product monograph including available dosage formats.

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 608 (Hidradenitis Suppurativa – Adult only)

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

A. A total abscess and nodule count of 3 or greater; AND

B. Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III; AND

C. Experienced an inadequate response to a 90-day trial of oral antibiotics.

Therapy must be prescribed by a practitioner with expertise in the management of patients with HS.

The recommended adult dosing regimen is 160mg at week 0, followed by 80mg at week 2, then 40mg at week 4, and 40mg weekly thereafter.

If there is no improvement after 12 weeks of treatment with adalimumab at the Health Canada approved dose, higher doses are not recommended and the prescriber should discontinue treatment.

Prescribers should be informed and stay current with a drug's official Health Canada approved product monograph including available dosage formats.

Maintenance/Renewal:

Maintenance therapy is funded for patients beyond the first 12 weeks in those who meet the Ministry initiation criteria and who have responded to treatment defined as at least a 50% reduction in abscesses and inflammatory nodule count with no increase in abscess count or draining fistula count relative to baseline.

Maintenance therapy beyond the second year is funded for patients using adalimumab for HS, where there is objective evidence of the preservation of treatment effect (i.e. the current abscess and inflammatory nodule count should be compared to the count prior to initiating treatment with adalimumab).

The recommended maintenance dose is 40mg weekly.

Prescribers should be informed and stay current with a drug's official Health Canada approved product monograph including available dosage formats.

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 609 (Plaque Psoriasis)

For the treatment of severe* plaque psoriasis in patients 18 years of age or older who have experienced failure, intolerance, or have a contraindication to adequate trials of several standard therapies**.

Claims for the first 6 months must be written by a dermatologist.

Monitoring of patients is required to determine if continuation of therapy beyond 12 weeks is required.

Patients not responding adequately at 12 weeks should have treatment discontinued.

* Definition of severe plaque psoriasis:

Body Surface Area (BSA) involvement of at least 10%, or involvement of the face, hands, feet or genital regions, AND

Psoriasis Area and Severity Index (PASI) score of at least 10 (not required if there is involvement of the face, hands, feet or genital regions), AND

Dermatology Life Quality Index (DLQI) score of at least 10.

** Definition of failure, intolerance or contraindication to adequate trials of standard therapies:

6 month trial of at least 3 topical agents including vitamin D analogues and steroids

12 week trial of phototherapy (unless not accessible)

6 month trial of at least 2 systemic, oral agents used alone or in combination

-Methotrexate 15-30mg per week
-Acitretin (could have been used with phototherapy)
-Cyclosporine

Maintenance/Renewal:

After 3 months of therapy, patients who respond to therapy should have:

-at least a 50% reduction in PASI, AND
-at least a 50% reduction in BSA involvement, AND
-at least a 5 point reduction in DLQI score

Approvals will only allow for standard dosing for adalimumab.

The recommended dose is an initial 80mg administered subcutaneously at week 0, followed by 40mg subcutaneously given every other week starting at week 1, as approved by Health Canada.

If the patient has not responded adequately after 12 weeks of treatment at the Health Canada approved dose, higher doses are not recommended, and the physician should consider switching to an alternative biologic agent.

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 611 (Uveitis – Adult and pediatric)

For the treatment of severe uveitis in patients meeting the following criteria:

A. Has experienced failure or intolerance to an oral corticosteroid (or topical corticosteroid for anterior uveitis) or where the use of corticosteroids is contraindicated, and has experienced failure or intolerance to at least one immunosuppressive therapy; AND

B. Treatment must be prescribed by an ophthalmologist specialized in uveitis or retinal disease, a uveitis specialist, or a retina specialist familiar with ocular inflammatory diseases.

Requests not meeting the above criteria may be considered on a case-by-case basis through the Exceptional Access Program.

The recommended adult dose is an initial 80mg administered subcutaneously at week 0, followed by 40mg subcutaneously given every other week starting at week 1, as approved by Health Canada. Note: Higher doses up to 40mg weekly may be considered in patients who have failed to respond to lower doses.

The recommended dose for pediatric patients (2 years of age or older) with anterior uveitis is:

Less than 30kg: 20mg every other week in combination with methotrexate

30kg or greater: 40mg every other week in combination with methotrexate

For patients 6 years of age or older and less than 30kg, an optional loading dose of 40mg at week 0 may be administered before starting maintenance therapy.

For patients 6 years of age or older and weighing 30kg or greater, an optional loading dose of 80mg at week 0 may be administered before starting maintenance therapy.

It should be noted that some adalimumab products may not be available as 20mg injectables.

Prescribers should be informed and stay current with a drug's official Health Canada approved product monograph including available dosage formats.

Maintenance/Renewals:

Maintenance therapy is funded for patients who meet the Ministry initiation criteria and who have experienced improvement and/or stability of vision and other treatment goals (e.g. reduction or control of ocular inflammation).

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 612 (Uveitis – Adult only)

For the treatment of severe uveitis in patients meeting the following criteria:

A. Has experienced failure or intolerance to an oral corticosteroid (or topical corticosteroid for anterior uveitis) or where the use of corticosteroids is contraindicated, and has experienced failure or intolerance to at least one immunosuppressive therapy; AND

B. Treatment must be prescribed by an ophthalmologist specialized in uveitis or retinal disease, a uveitis specialist, or a retina specialist familiar with ocular inflammatory diseases.

Requests not meeting the above criteria may be considered on a case-by-case basis through the Exceptional Access Program.

The recommended adult dose is an initial 80mg administered subcutaneously at week 0, followed by 40mg subcutaneously given every other week starting at week 1, as approved by Health Canada. Note: Higher doses up to 40mg weekly may be considered in patients who have failed to respond to lower doses.

Prescribers should be informed and stay current with a drug's official Health Canada approved product monograph including available dosage formats.

Maintenance/Renewals:

Maintenance therapy is funded for patients who meet the Ministry initiation criteria and who have experienced improvement and/or stability of vision and other treatment goals (e.g. reduction or control of ocular inflammation).

LU Authorization Period: 1 year

New Single Source Products (Continued)

Ontario

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02467895	Aermony Respiclick	55mcg/ Actuation	Pd Inh-60 Dose Pk	FLUTICASONE PROPIONATE	TEV	16.9560/Pk
02467909	Aermony Respiclick	113mcg/ Actuation	Pd Inh-60 Dose Pk	FLUTICASONE PROPIONATE	TEV	30.9619/Pk
02467917	Aermony Respiclick	232mcg/ Actuation	Pd Inh-60 Dose Pk	FLUTICASONE PROPIONATE	TEV	48.1524/Pk

New Multi-Source Products

Where applicable, please consult the respective brand reference product's drug profile on the ODB e-Formulary for the details of the Limited Use (LU) code and criteria, and/or any associated Therapeutic Notes (TN).

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02450860	ACH-Quetiapine Fumarate XR	50mg	ER Tab	ACH	0.2501
02450879	ACH-Quetiapine Fumarate XR	150mg	ER Tab	ACH	0.4926
02450887	ACH-Quetiapine Fumarate XR	200mg	ER Tab	ACH	0.6661
02450895	ACH-Quetiapine Fumarate XR	300mg	ER Tab	ACH	0.9776
02450909	ACH-Quetiapine Fumarate XR	400mg	ER Tab	ACH	1.3270

(Interchangeable with Seroquel XR – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02297574	Apo-Perindopril-Indapamide	4mg & 1.25mg	Tab	APX	0.2556

(Interchangeable with Coversyl Plus – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02453061	Apo-Perindopril-Indapamide	8mg & 2.5mg	Tab	APX	0.2859

(Interchangeable with Coversyl Plus HD – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02389940	Jamp Telmisartan-HCT	80mg & 12.5mg	Tab	JPC	0.2098
02389959	Jamp Telmisartan-HCT	80mg & 25mg	Tab	JPC	0.2098

(Interchangeable with Micardis Plus – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02476177	Mar-Flecainide	50mg	Tab	MAR	0.1389
02476185	Mar-Flecainide	100mg	Tab	MAR	0.2779

(Interchangeable with Tambocor – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02496828	Mint-Leucovorin	5mg	Tab	MIN	3.6776

(Interchangeable with Leucovorin Calcium – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02488434	NRA-Sertraline	25mg	Cap	NRA	0.1516
02488442	NRA-Sertraline	50mg	Cap	NRA	0.3032
02488450	NRA-Sertraline	100mg	Cap	NRA	0.3303

(Interchangeable with Zoloft – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02503131	PMS-Fluticasone	250mcg/Actuation	Metered Dose Inh-120 Dose Pk	PMS	67.5300

(Interchangeable with Flovent HFA – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02436299	Celecoxib	100mg	Cap	SAI	0.1279
02436302	Celecoxib	200mg	Cap	SAI	0.2558

(Interchangeable with Celebrex – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02506882	Sandoz Ciprofloxacin/ Dexamethasone	0.3% w/v & 0.1% w/v	Otic Susp-7.5mL Pk (With Preservative)	SDZ	14.4203

(Interchangeable with Ciprodex – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02475421	Sandoz Silodosin	4mg	Cap	SDZ	1.4225
02475448	Sandoz Silodosin	8mg	Cap	SDZ	1.4225

(Interchangeable with Rapaflo – LU)

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02491397	Apo-Abiraterone Film Coated Tablets	250mg	Tab	APX	26.0313
02491400	Apo-Abiraterone Film Coated Tablets	500mg	Tab	APX	52.0625

(Interchangeable with Zytiga)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02511150	Ertapenem for Injection	1g	Pd for Inj Sol-Vial Pk	DRR	52.2650/ Vial

(Interchangeable with Invanz)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02477114	Reddy-Abiraterone	250mg	Tab	DRR	26.0313

(Interchangeable with Zytiga)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02502305	Jamp Abiraterone	250mg	Tab	JPC	26.0313

(Interchangeable with Zytiga)

New Off-Formulary Interchangeable (OFI) Products (Continued)

Ontario

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02469669	Jamp-Sildenafil R	20mg	Tab	JPC	7.2940

(Interchangeable with Revatio)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02503506	Jamp Sildenafil Tablets	100mg	Tab	JPC	9.2000

(Interchangeable with Viagra)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02503980	Mar-Abiraterone	250mg	Tab	MAR	26.0313
02503999	Mar-Abiraterone	500mg	Tab	MAR	52.0625

(Interchangeable with Zytiga)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02494132	Nat-Abiraterone	250mg	Tab	NAT	26.0313

(Interchangeable with Zytiga)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02492601	PMS-Abiraterone	250mg	Tab	PMS	26.0313
02501503	PMS-Abiraterone	500mg	Tab	PMS	52.0625

(Interchangeable with Zytiga)

New Off-Formulary Interchangeable (OFI) Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02502917	PMS-Iron Sucrose	20mg/mL	Inj Sol-5mL Pk (Preservative-Free)	PMS	31.8750

(Interchangeable with Venofer)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02380897	PMS-Nabilone	0.25mg	Cap	PMS	1.4660

(Interchangeable with Cesamet)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02486393	Sandoz Abiraterone	250mg	Tab	SDZ	26.0313

(Interchangeable with Zytiga)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02479540	Rivastigmine Patch 5	4.6mg/24hr	Transdermal Patch	STR	3.9773/ Patch

(Interchangeable with Exelon Patch 5)

New Off-Formulary Interchangeable (OFI) Products (Continued)

Ontario

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02479559	Rivastigmine Patch 10	9.5mg/24hr	Transdermal Patch	STR	3.9773/ Patch

(Interchangeable with Exelon Patch 10)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02479567	Rivastigmine Patch 15	13.3mg/24hr	Transdermal Patch	STR	3.9773/ Patch

(Interchangeable with Exelon Patch 15)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02499282	Taro-Dasatinib	20mg	Tab	TAR	32.8823
02499304	Taro-Dasatinib	50mg	Tab	TAR	67.1783
02499312	Taro-Dasatinib	70mg	Tab	TAR	72.9337
02499320	Taro-Dasatinib	80mg	Tab	TAR	117.3257
02499339	Taro-Dasatinib	100mg	Tab	TAR	132.2670
02499347	Taro-Dasatinib	140mg	Tab	TAR	141.8806

(Interchangeable with Sprycel)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02507315	Taro-Deferasirox (Type J)	90mg	Tab	TAR	9.2583
02507323	Taro-Deferasirox (Type J)	180mg	Tab	TAR	18.5173
02507331	Taro-Deferasirox (Type J)	360mg	Tab	TAR	37.0370

(Interchangeable with Jadenu)

Addition of Reason For Use Code

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02455331	Brenzys	50mg/mL	Inj Sol-Pref Autoinj	SAM
02455323	Brenzys	50mg/mL	Inj Sol-Pref Syr	SAM

The LU criteria of the Erelzi products that currently have these 3 LU codes are modified in order to align with the criteria here.

Reason for Use Code and Clinical Criteria

Code 591 (Plaque Psoriasis)

For the treatment of severe* plaque psoriasis in patients who have experienced failure, intolerance, or have a contraindication to adequate trials of several standard therapies**.

Claims for the first 6 months must be written by a dermatologist.

Monitoring of patients is required to determine if continuation of therapy beyond 12 weeks is required.

Patients not responding adequately at 12 weeks should have treatment discontinued.

* Definition of severe plaque psoriasis:

Body Surface Area (BSA) involvement of at least 10%, or involvement of the face, hands, feet or genital regions, AND

Psoriasis Area and Severity Index (PASI) score of at least 10 (not required if there is involvement of the face, hands, feet or genital regions), AND

Dermatology Life Quality Index (DLQI) score of at least 10.

** Definition of failure, intolerance or contraindication to adequate trials of standard therapies:

6 month trial of at least 3 topical agents including vitamin D analogues and steroids, AND

12 week trial of phototherapy (unless not accessible), AND

6 month trial of at least 2 systemic, oral agents used alone or in combination

- Methotrexate 15-30mg per week
- Acitretin (could have been used with phototherapy)
- Cyclosporine

Maintenance/Renewal:

After 3 months of therapy, patients who respond to therapy should have:

-At least a 50% reduction in PASI, AND
-at least a 50% reduction in BSA involvement, AND
-at least a 5 point reduction in DLQI score

Approvals will only allow for standard dosing for etanercept:

The recommended dose is 50mg subcutaneous twice weekly for 12 weeks followed by maintenance therapy at 25-50mg subcutaneous once weekly as approved by Health Canada. If the patient has not responded adequately after 12 weeks of treatment at the Health Canada approved dose, higher doses are not recommended and the physician should consider switching to an alternative biologic agent.

Prescribers should be informed and stay current with a drug's official Health Canada approved product monograph including available dosage formats.

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 563 (Psoriatic Arthritis)

For the treatment of psoriatic arthritis in patients who have severe active disease (greater than or equal to 5 swollen joints and radiographic evidence of psoriatic arthritis) despite treatment with methotrexate (20mg/week) for at least 3 months and one of leflunomide (20mg/day) or sulfasalazine (1g twice daily) for at least 3 months.

Maintenance/Renewal:

After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 20% reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year.

For renewals beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

Therapy must be prescribed by a rheumatologist or a physician with expertise in rheumatology.

The recommended dosing regimen is 50mg per week or 25mg twice weekly.

Prescribers should be informed and stay current with a drug's official Health Canada approved product monograph including available dosage formats.

LU Authorization Period: 1 year

Reason for Use Code and Clinical Criteria

Code 514 (Polyarticular Juvenile Idiopathic Arthritis)

For the treatment of polyarticular juvenile idiopathic arthritis (pJIA) in patients who have active disease (greater than or equal to 3 swollen joints and greater than or equal to 5 active joints) despite a trial of optimal doses of subcutaneously administered methotrexate (i.e. 15mg/m2 per week) for at least 3 months. If the patient is unable to tolerate or has a contraindication to subcutaneous methotrexate, the nature of the intolerance or contraindication should be documented.

Maintenance/Renewal:

After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 20 percent reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. For funding beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

Therapy must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

The recommended dosing regimen for pediatric patients ages 4 to 17 years with active pJIA is 0.8mg/kg per week (up to a maximum of 50mg per week).

Prescribers should be informed and stay current with a drug's official Health Canada approved product monograph including available dosage formats.

LU Authorization Period: 1 year

Relisting of Temporary Benefit Product

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
09858123	Phenelzine Sulfate Tablets USP	15mg	Tab	PHENELZINE SULFATE	LUP	0.5908

New Palliative Care Facilitated Access Products

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
09857653	Doloral 1	1mg/mL	O/L	MORPHINE HYDROCHLORIDE	LAA	0.0313/mL
09857654	Doloral 5	5mg/mL	O/L	MORPHINE HYDROCHLORIDE	LAA	0.0603/mL

Manufacturer Name Changes

DIN/PIN	Brand Name	Strength	Dosage Form	Current Mfr	New Mfr
02162660	Toradol	10mg	Tab	HLR	AAP
00155225	Ponstan	250mg	Cap	PFI	AAP
02216345	Salagen	5mg	Tab	PFI	AMD
02248808	Adderall XR	5mg	ER Cap	SHI	TAK
02248809	Adderall XR	10mg	ER Cap	SHI	TAK
02248810	Adderall XR	15mg	ER Cap	SHI	TAK
02248811	Adderall XR	20mg	ER Cap	SHI	TAK
02248812	Adderall XR	25mg	ER Cap	SHI	TAK
02248813	Adderall XR	30mg	ER Cap	SHI	TAK
02287145	Fosrenol	250mg	Chew Tab	SHI	TAK
02287153	Fosrenol	500mg	Chew Tab	SHI	TAK
02287161	Fosrenol	750mg	Chew Tab	SHI	TAK
02287188	Fosrenol	1000mg	Chew Tab	SHI	TAK
02409100	Intuniv XR	1mg	ER Tab	SHI	TAK
02409119	Intuniv XR	2mg	ER Tab	SHI	TAK
02409127	Intuniv XR	3mg	ER Tab	SHI	TAK
02409135	Intuniv XR	4mg	ER Tab	SHI	TAK

Product Brand and Manufacturer Name Changes

DIN/PIN	Current Brand Name	Current Mfr	New Brand Name	New Mfr	Strength	Dosage Form
00740799	Apo-Trimip	APX	Trimipramine	AAP	12.5mg	Tab
02248763	Apo-Atenidone	APX	AA-Atenidone	AAP	50 & 25mg	Tab
02248764	Apo-Atenidone	APX	AA-Atenidone	AAP	100 & 25mg	Tab

Drug Benefit Price (DBP) Changes

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP/Unit Price
02172062	Synthroid	0.025mg	Tab	ABB	0.0999
02172070	Synthroid	0.05mg	Tab	ABB	0.0686
02172089	Synthroid	0.075mg	Tab	ABB	0.1080
02172097	Synthroid	0.088mg	Tab	ABB	0.1080
02172100	Synthroid	0.1mg	Tab	ABB	0.0847
02171228	Synthroid	0.112mg	Tab	ABB	0.1138
02172119	Synthroid	0.125mg	Tab	ABB	0.1154
02172127	Synthroid	0.15mg	Tab	ABB	0.0910
02172135	Synthroid	0.175mg	Tab	ABB	0.1236
02172143	Synthroid	0.2mg	Tab	ABB	0.0967
02172151	Synthroid	0.3mg	Tab	ABB	0.1333
02241795	Procytox	25mg	Tab	BAX	0.3545
02241796	Procytox	50mg	Tab	BAX	0.4773
00443832	Depakene	50mg/mL	O/L	BGP	0.1301/mL
00596418	Epival	125mg	Ent Tab	BGP	0.3309
00596426	Epival	250mg	Ent Tab	BGP	0.5950
00596434	Epival	500mg	Ent Tab	BGP	1.1905
02269074	Lipidil EZ	48mg	Tab	FOU	0.4608
02269082	Lipidil EZ	145mg	Tab	FOU	1.1801
02333856	Janumet	500mg & 50mg	Tab	MEK	1.7785
02333864	Janumet	850mg & 50mg	Tab	MEK	1.7785
02333872	Janumet	1000mg & 50mg	Tab	MEK	1.7785
02416786	Janumet XR	500mg & 50mg	ER Tab	MEK	1.7785
02416794	Janumet XR	1000mg & 50mg	ER Tab	MEK	1.7785
02416808	Janumet XR	1000mg & 100mg	ER Tab	MEK	3.5568
02424622	Posanol	100mg	DR Tab	MEK	51.4244
02374803	Saphris	5mg	SL Tab	MEK	1.5910
02374811	Saphris	10mg	SL Tab	MEK	1.5910
02388839	Januvia	25mg	Tab	MFC	3.2787
02388847	Januvia	50mg	Tab	MFC	3.2787
02303922	Januvia	100mg	Tab	MFC	3.2787
02293269	Campral	333mg	DR Tab	MYL	0.8806
02231506	PMS-Diclofenac	50mg	Sup	PMS	0.8545
02493357	Riva Leucovorin	5mg	Tab	RIA	3.6776
02261928	Sandoz Diclofenac	50mg	Sup	SDZ	0.8545

Drug Benefit Price (DBP) Changes (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP/Unit Price
02470438	Sandoz Perindopril Erbumine/Indapamide	4mg & 1.25mg	Tab	SDZ	0.2556
02470446	Sandoz Perindopril Erbumine/IndapamideHD	8mg & 2.5mg	Tab	SDZ	0.2859
02245345	Androgel	1%	2.5g Foil Packet	SPH	2.3974
02245346	Androgel	1%	5.0g Foil Packet	SPH	4.2393
02240432	Teveten	400mg	Tab	SPH	0.7790
02243942	Teveten	600mg	Tab	SPH	1.1910
02253631	Teveten Plus	600mg & 12.5mg	Tab	SPH	1.1910
02422050	Latuda	20mg	Tab	SUO	4.9000
02387751	Latuda	40mg	Tab	SUO	4.9000
02413361	Latuda	60mg	Tab	SUO	4.9000
02387778	Latuda	80mg	Tab	SUO	4.9000
02387786	Latuda	120mg	Tab	SUO	4.9000
02481901	Taro-Ciprofloxacin/ Dexamethasone	0.3% w/v & 0.1% w/v	Otic Susp-7.5mL Pk (With Preservative)	TAR	14.4203
02464020	Teva-Perindopril Erbumine/Indapamide	4mg & 1.25mg	Tab	TEV	0.2556
02464039	Teva-Perindopril Erbumine/Indapamide	8mg & 2.5mg	Tab	TEV	0.2859
02165503	Prevacid	15mg	DR Cap	TPA	2.1501
02165511	Prevacid	30mg	DR Cap	TPA	2.1501

Discontinued Products

(Some products will remain on Formulary for six months to facilitate depletion of supply)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02014165	Uniphyl	400mg	SR Tab	ELV
02014181	Uniphyl	600mg	SR Tab	ELV
02213230	Eltroxin	0.3mg	Tab	GLW
02383039	Mylan-Esomeprazole	20mg	DR Tab	MYL
02383047	Mylan-Esomeprazole	40mg	DR Tab	MYL
00417289	Visken	15mg	Tab	NOV
00579335	Cortifoam	10%	Rect Aero-15g Pk	PAL
01926454	Nitrol	2%	Oint	PAL
02241674	Plan B	0.75mg	Tab-2 Tabs Pk	PAL
00621935	Statex	20mg/mL	Oral Drops	PAL
00180408	Aldactazide-25	25mg & 25mg	Tab	PFI
00594377	Aldactazide-50	50mg & 50mg	Tab	PFI
02132699	Colestid Orange		Gran-7.5g Pk	PFI
00607142	ERYC	250mg	Ent Pel Cap	PFI

Delisted Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02243987	Apo-Amoxi Clav	50mg & 12.5mg/mL	O/L	APX
02321459	Apo-Entacapone	200mg	Tab	APX
02476614	Apo-HYDROmorphone CR	3mg	CR Cap	APX
02476622	Apo-HYDROmorphone CR	4.5mg	CR Cap	APX
02476657	Apo-HYDROmorphone CR	12mg	CR Cap	APX
02476673	Apo-HYDROmorphone CR	24mg	CR Cap	APX
02476681	Apo-HYDROmorphone CR	30mg	CR Cap	APX
02365499	Apo-Naratriptan	1mg	Tab	APX
02264846	Tramacet	37.5mg & 325mg	Tab	JAN
02163934	Tylenol with Codeine No. 2	300mg & 15mg & 15mg	Tab	JAN
02163926	Tylenol with Codeine No. 3	300mg & 15mg & 30mg	Tab	JAN
02349469	Ultram	50mg	Tab	JAN
09858116	Salbutamol Aldo-Union	100mcg/Metered Dose	Inh-200 Dose Pk	JPC
01964968	PMS-Dexamethasone	0.75mg	Tab	PMS
09858119	Salbuhaler	100mcg/Metered Dose	Inh-200 Dose Pk	SDZ
02247439	Sandoz Bisoprolol	5mg	Tab	SDZ
02247440	Sandoz Bisoprolol	10mg	Tab	SDZ
09858115	Salamol CFC-Free Inhaler	100mcg/Metered Dose	Inh-200 Dose Pk	TEV
02410818	Jetrea	2.5mg/mL	Inj Sol-0.2mL Vial Pk (Preservative-Free)	THO