Ontario

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – April 2024
Effective April 30, 2024

Drug Programs Policy and Strategy Branch
Health Programs and Delivery Division
Ministry of Health

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New Single Source Products

Generic Name: MESALAZINE

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02465752	Octasa	800mg	DR Tab	TIP	1.1358
02529610	Octasa	1600mg	DR Tab	TIP	2.3740

Generic Name: ADALIMUMAB

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02542315	Hyrimoz	20mg/0.2mL	Inj Sol-0.2mL Pref Syr (Preservative-Free)	SDZ	235.6350/ Pref Syr
02542323	Hyrimoz	40mg/0.4mL	Inj Sol-0.4mL Pref Syr (Preservative-Free)	SDZ	471.2700/ Pref Syr
02542331	Hyrimoz	40mg/0.4mL	Inj Sol-0.4mL Pref Pen (Preservative-Free)	SDZ	471.2700/ Pref Pen
02542358	Hyrimoz	80mg/0.8mL	Inj Sol-0.8mL Pref Syr (Preservative-Free)	SDZ	942.5400/ Pref Syr
02542366	Hyrimoz	80mg/0.8mL	Inj Sol-0.8mL Pref Pen (Preservative-Free)	SDZ	942.5400/ Pref Pen

The Limited Use (LU) codes 600-607, 609 and 611 and clinical criteria are the same as for the currently listed Hyrimoz (adalimumab) products.

New Single Source Products (Continued)

Generic Name: USTEKINUMAB

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02543036	Jamteki	45mg/0.5mL	Inj Sol-0.5mL Pref Syr Pk	JPC	2755.8840/ Pref Syr
02543044	Jamteki	90mg/mL	Inj Sol-1mL Pref Syr Pk	JPC	2755.8840/ Pref Syr

Reason For Use Code and Clinical Criteria

Code 668

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

New Single Source Products (Continued)

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

Recommended dose:

The recommended dose of ustekinumab is 45mg administered subcutaneously at weeks 0 and 4, then every 12 weeks thereafter.

Alternatively, 90mg may be used in patients with a body weight of over 100kg. In patients weighing over 100kg, both the 45mg and 90mg doses were shown to be efficacious. However, 90mg was efficacious in a higher percentage of these patients.

For patients who inadequately respond to dosing every 12 weeks, consideration may be given to treating as often as every 8 weeks.

If the patient has not responded after 12 weeks of treatment, the prescriber should consider switching to an alternative biologic agent.

LU Authorization Period: 1 year

Code 669

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.

New Single Source Products (Continued)

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 45mg administered subcutaneously at weeks 0 and 4, then every 12 weeks thereafter. Alternatively, 90mg may be used in patients with a body weight greater than 100kg.

Ustekinumab may be used alone or in combination with methotrexate (MTX).

LU Authorization Period: 1 year

Generic Name: USTEKINUMAB

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02544180	Wezlana	45mg/0.5mL	Inj Sol-0.5mL Pref Syr Pk	AMG	2755.8840/ Pref Syr
02544199	Wezlana	90mg/mL	Inj Sol-1mL Pref Syr Pk	AMG	2755.8840/ Pref Syr
02544202	Wezlana	45mg/0.5mL	Inj Sol-0.5mL Vial Pk	AMG	2755.8840/ Vial
02544210*	Wezlana I.V.	130mg/26mL	Inj Sol-26mL Vial Pk	AMG	1248.0000/ Vial

*Only LU Codes 671 and 672 apply to this product

Code 669

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.

New Single Source Products (Continued)

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 45mg administered subcutaneously at weeks 0 and 4, then every 12 weeks thereafter. Alternatively, 90mg may be used in patients with a body weight greater than 100kg.

Ustekinumab may be used alone or in combination with methotrexate (MTX).

LU Authorization Period: 1 year

Code 670

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.

New Single Source Products (Continued)

** 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

Recommended dose:

The recommended dose of ustekinumab for adult patients is 45mg administered subcutaneously at weeks 0 and 4, then every 12 weeks thereafter.

Alternatively, 90mg may be used in patients with a body weight of over 100kg. In patients weighing over 100kg, both the 45mg and 90mg doses were shown to be efficacious. However, 90mg was efficacious in a higher percentage of these patients.

Refer to the appropriate product monograph for dosing in pediatric patients weighing less than 60kg.

For patients who inadequately respond to dosing every 12 weeks, consideration may be given to treating as often as every 8 weeks.

If the patient has not responded after 12 weeks of treatment, the prescriber should consider switching to an alternative biologic agent.

LU Authorization Period: 1 year

New Single Source Products (Continued)

Code 671

For the treatment of moderate to severe ulcerative colitis in patients who meet the following criteria:

A. Mayo score greater than or equal to 6 with an endoscopic subscore* of at least 2 (or other validated disease activity score confirming moderate to severe disease); AND

B. Failed conventional treatment with a corticosteroid (prednisone 40-60mg/day [or equivalent]) for a minimum of 14 days (or intravenous corticosteroid for 1 week); OR

   Responded to/stabilized on conventional treatment with a corticosteroid, with or without an immunosuppressant (e.g., azathioprine, 6-mercaptopurine); OR

   Conventional treatment with a corticosteroid is contraindicated; AND

C. Ustekinumab is being used to induce remission or as a steroid-sparing maintenance therapy.

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

The recommended induction dosing is a single intravenous (IV) dose based on body weight (for patients less than or equal to 55kg a dose of ustekinumab IV 260mg, for patients greater than 55kg to less than or equal to 85kg a dose of ustekinumab IV 390mg, and for patients greater than 85kg a dose of ustekinunab IV 520mg).

The recommended maintenance dosing regimen is 90mg administered subcutaneously at week 8 following the IV induction dose, followed by subsequent doses every 8 weeks thereafter.

Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit 16 weeks after the IV induction dose.

Maintenance/Renewal:

Maintenance therapy is funded for patients who met the initiation criteria and have demonstrated a treatment response or are in remission.

Examples of treatment response include clinically meaningful reductions in disease activity scores (e.g., Mayo score less than 6), along with improvements in endoscopic findings and reduction or discontinuation of corticosteroids.

Prescribers may wish to consider other funded alternatives for patients unable to discontinue corticosteroid therapy.

New Single Source Products (Continued)

Exclusion criteria (initial and renewal coverage):

- Combination therapy with another biologic used to treat inflammatory disease will not be funded.

Patients with mild ulcerative colitis (e.g., Mayo score less than 6) may be considered on a case-by-case basis through the Exceptional Access Program.

LU Authorization Period: 1 year

Code 672

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 (or other validated disease activity score confirming moderate to severe luminal Crohn's disease); AND
B. Failed conventional treatment with a corticosteroid (prednisone 40-60mg/day [or equivalent]) for a minimum of 14 days (or intravenous corticosteroid for 1 week); OR

   Responded to/stabilized on conventional treatment with a corticosteroid, with or without an immunosuppressant (e.g., azathioprine, 6-mercaptopurine, methotrexate); OR

   Conventional treatment with a corticosteroid is contraindicated; AND
C. Ustekinumab is being used to induce remission or as a steroid-sparing maintenance therapy.

The recommended induction dosing is a single intravenous (IV) dose based on body weight (for patients less than or equal to 55kg a dose of ustekinumab IV 260mg, for patients greater than 55kg to less than or equal to 85kg a dose of ustekinumab IV 390mg, and for patients greater than 85kg a dose of ustekinumab IV 520mg).

The recommended maintenance dosing regimen is 90mg administered subcutaneously at week 8 following the IV induction dose, followed by subsequent doses every 8 weeks thereafter. Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit 16 weeks after the IV induction dose.

New Single Source Products (Continued)

Maintenance/Renewal:

Maintenance therapy is funded for patients who met the initiation criteria and have demonstrated a treatment response or are in remission. Examples of treatment response include clinically meaningful reductions in disease activity scores (e.g., HBI score decrease greater than or equal to 50% from pre-treatment measurement), along with improvements in endoscopic findings and reduction or discontinuation of corticosteroids.

Prescribers may wish to consider other funded alternatives for patients unable to discontinue corticosteroid therapy.

Exclusion criteria (initial and renewal coverage):

- Combination therapy with another biologic used to treat inflammatory bowel disease will not be funded.

Patients with mild Crohn's disease (e.g., HBI less than 7) may be considered on a case-by-case basis through the Exceptional Access Program.

Patients with fistulising Crohn’s disease may be considered on a case-by-case basis through the Exceptional Access Program.

LU Authorization Period: 1 year

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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
02536021	Amoxicillin/Clav	500mg & 125mg	Tab	SAI	0.3778

(Interchangeable with Clavulin – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02536048	Amoxicillin/Clav	875mg & 125mg	Tab	SAI	0.5551

(Interchangeable with Clavulin (BID) – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02347261	Auro-Cefprozil	125mg/5mL	Oral Susp-75mL Pk	AUR	7.2750/Pk
09858332	Auro-Cefprozil	125mg/5mL	Oral Susp-100mL Pk	AUR	9.7000/Pk
02347288	Auro-Cefprozil	250mg/5mL	Oral Susp-75mL Pk	AUR	14.5350/Pk
09858333	Auro-Cefprozil	250mg/5mL	Oral Susp-100mL Pk	AUR	19.3800/Pk

(Interchangeable with Cefzil – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02536064	Candesartan/HCTZ	32mg & 12.5mg	Tab	SAI	0.2156

(Interchangeable with Atacand Plus – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02539802	Hydralazine	10mg	Tab	SAI	0.0355
02539810	Hydralazine	25mg	Tab	SAI	0.0609
02539829	Hydralazine	50mg	Tab	SAI	0.0956

(Interchangeable with Apresoline – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02535246	Jamp Gabapentin Capsules	100mg	Cap	JPC	0.0416
02535254	Jamp Gabapentin Capsules	300mg	Cap	JPC	0.1012
02535262	Jamp Gabapentin Capsules	400mg	Cap	JPC	0.1206

(Interchangeable with Neurontin – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02516292	Jamp Rivaroxaban	10mg	Tab	JPC	0.7175
02516306	Jamp Rivaroxaban	15mg	Tab	JPC	0.7175
02516314	Jamp Rivaroxaban	20mg	Tab	JPC	0.7175

(Interchangeable with Xarelto – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02345269	Jamp Topiramate Tablets	100mg	Tab	JPC	0.4583

(Interchangeable with Topamax – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02469170	Lupin-Cephalexin	125mg/5mL	Pd for Oral Susp	LUP	0.1535/mL
02469189	Lupin-Cephalexin	250mg/5mL	Pd for Oral Susp	LUP	0.2573/mL

(Interchangeable with Keflex – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02537397	Metoclopramide Hydrochloride Injection	5mg/mL	Inj Sol (Preservative Free)	JPC	2.3748/mL

(Interchangeable with Metoclopramide HCL Injection – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02536420	NRA-Ezetimibe Tablets	10mg	Tab	NRA	0.1811

(Interchangeable with Ezetrol – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02538466	NRA-Topiramate	25mg	Tab	NRA	0.2433
02538458	NRA-Topiramate	100mg	Tab	NRA	0.4583
02538474	NRA-Topiramate	200mg	Tab	NRA	0.6748

(Interchangeable with Topamax – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02255510	Riva-Fluconazole	150mg	Cap	RIA	3.9424

(Interchangeable with Diflucan-150 – LU)

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02533642	Apo-Methadone	1mg	Tab	APX	0.1399
09858328*	Apo-Methadone	1mg	Tab	APX	0.1399
02533650	Apo-Methadone	5mg	Tab	APX	0.4659
09858329*	Apo-Methadone	5mg	Tab	APX	0.4659
02533669	Apo-Methadone	10mg	Tab	APX	0.7454
09858330*	Apo-Methadone	10mg	Tab	APX	0.7454
02533677	Apo-Methadone	25mg	Tab	APX	1.3850
09858331*	Apo-Methadone	25mg	Tab	APX	1.3850

(Interchangeable with Metadol)

*Product Identification Numbers for Facilitated Access Palliative Care

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02540592	Jamp Zolpidem ODT	5mg	ODT	JPC	1.1827
02540606	Jamp Zolpidem ODT	10mg	ODT	JPC	1.1883

(Interchangeable with Sublinox)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02541696	PMS-Perindopril-Amlodipine	3.5mg & 2.5mg	Tab	PMS	0.8075
02541718	PMS-Perindopril-Amlodipine	7mg & 5mg	Tab	PMS	0.8925
02541726	PMS-Perindopril-Amlodipine	14mg & 10mg	Tab	PMS	0.9775

(Interchangeable with Viacoram)

Temporary Benefits

DIN/PIN	Product Name	Strength	Dosage Form	Generic Name	Mfr	DBP
09858334	Colesevelam	625mg	Tab	COLESEVELAM HYDROCHLORIDE	GLP	0.5931

Same TN as the currently listed colesevelam tablets.

Revision of Limited Use Criteria

DIN/PIN	Product Name	Strength	Dosage Form	Mfr
02320673	Stelara	45mg/0.5mL	Inj Sol-Pref Syr Pk	JAN
02320681	Stelara	90mg/mL	Inj Sol-Pref Syr Pk	JAN

Revised Clinical Criteria

Code 419

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**, but only for patients established on Stelara (ustekinumab) therapy prior to April 30, 2024.

* 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

Revision of Limited Use Criteria (Continued)

Approvals will only allow for standard dosing for Stelara 45mg to be administered at weeks 0, 4 and every 12 weeks thereafter. Alternatively, 90mg may be used in patients with a body weight of over 100kg. In patients weighing over 100kg, both the 45mg and 90mg doses were shown to be efficacious. However, 90mg was efficacious in a higher percentage of these patients. If the patient has not responded after 12 weeks of treatment, the physician should consider switching to an alternative biologic agent.

LU Authorization Period: 1 year

Product Name and Manufacturer Name Changes

DIN/PIN	Current Product Name	Current Mfr	New Product Name	New Mfr	Strength	Dosage Form
02473488	AA-Telmisartan-Amlodipine	AAP	Apo-Telmisartan-Amlodipine	APX	80mg & 5mg	Tab
02473496	AA-Telmisartan-Amlodipine	AAP	Apo-Telmisartan-Amlodipine	APX	80mg & 10mg	Tab

Drug Benefit Price (DBP) Changes

To view the DBP changes by DIN/PIN, the ministry has posted an Excel file with the details of the listing changes for download and review (Edition 43: Summary of Changes–Drug Benefit Price Changes–April 2024). It is accessible from the ministry's website:

https://www.ontario.ca/document/ontario-drug-benefit-odb-formularycomparative-drug-index-cdi-and-monthly-formulary-0

Discontinued Products

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

DIN/PIN	Product Name	Strength	Dosage Form	Mfr
02230621	Opticrom	2%	Oph Sol	ALL
02230619	Pediapred Oral Liquid	6.7mg/5mL	O/L	SAV
02278081	PMS-Famciclovir	125mg	Tab	PMS
02278103	PMS-Famciclovir	250mg	Tab	PMS
02459779	Repatha	120mg/mL	Inj Sol-Pref Cart of 3.5mL Pk	AMG
00027944	Valisone	0.1%	Scalp Lot	VAE
02451131	Zepatier	50mg & 100mg	Tab	MEK

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Delisted Products

DIN/PIN	Product Name	Strength	Dosage Form	Mfr
02283131	Altace HCT	2.5mg & 12.5mg	Tab	SAV
02283158	Altace HCT	5mg & 12.5mg	Tab	SAV
02194058	Aristocort R	0.1%	Cr	VAL
02432463	Lodalis	3.75g/Pk	Pd for Oral Susp	VAL
02163527	Minitran	0.4mg/Hr/13.3 Sq Cm	Patch	GRA
02163535	Minitran	0.6mg/Hr/20 Sq Cm	Patch	GRA
02338432	Prezista	75mg	Tab	JAN
02369753	Prezista	150mg	Tab	JAN
02324024	Prezista	600mg	Tab	JAN
02393050	Prezista	800mg	Tab	JAN
02236950	Risperdal	1mg/mL	O/L	JAN
02231347	Sporanox	10mg/mL	Oral Sol	JAN