Ontario

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – January 2023
Effective January 31, 2023

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

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New Single Source Products

Generic Name: INSULIN ASPART

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02520974	Kirsty	100U/mL	Inj Sol-5x3mL Pref Pen Pk	BGP	42.7125/Pk

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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
02525348	Amoxicillin Capsules BP	250mg	Cap	SAI	0.0672
02525356	Amoxicillin Capsules BP	500mg	Cap	SAI	0.1308

(Interchangeable with Amoxil – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02482630	Apo-Ticagrelor	90mg	Tab	APX	0.3960

(Interchangeable with Brilinta – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02486806	Auro-Apixaban	2.5mg	Tab	AUR	0.4084

(Interchangeable with Eliquis DIN 02377233 – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
09858239	Auro-Apixaban	2.5mg	Tab	AUR	0.4084

(Interchangeable with Eliquis PIN 09857463 – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02486814	Auro-Apixaban	5mg	Tab	AUR	0.4084

(Interchangeable with Eliquis – LU)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02530007	Auro-Tofacitinib	5mg	Tab	AUR	5.9897
02530015	Auro-Tofacitinib	10mg	Tab	AUR	21.1718

(Interchangeable with Xeljanz – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02528037	Jamp Diltiazem CD	120mg	CD Cap	JPC	0.3634
02528045	Jamp Diltiazem CD	180mg	CD Cap	JPC	0.4824
02528053	Jamp Diltiazem CD	240mg	CD Cap	JPC	0.6399
02528061	Jamp Diltiazem CD	300mg	CD Cap	JPC	0.7999

(Interchangeable with Cardizem CD – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02245946	Jamp-Docusate Sodium	100mg	Cap	JPC	0.0328

(Interchangeable with Colace – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02519461	Jamp Efavirenz/Emtricitabine/ Tenofovir Disoproxil Fumarate	600mg/200mg/300mg	Tab	JPC	11.3300

(Interchangeable with Atripla – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02520354	Jamp Linezolid	600mg	Tab	JPC	19.3041

(Interchangeable with Zyvoxam – LU)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02527200	Jamp Perindopril Erbumine	2mg	Tab	JPC	0.1632
02527219	Jamp Perindopril Erbumine	4mg	Tab	JPC	0.2042
02527227	Jamp Perindopril Erbumine	8mg	Tab	JPC	0.2831

(Interchangeable with Coversyl – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02495449	Mint-Apixaban	5mg	Tab	MIN	0.4084

(Interchangeable with Eliquis – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02522225	Mint-Quetiapine XR	400mg	ER Tab	MIN	1.3270

(Interchangeable with Seroquel XR – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02526379	Mint-Ranitidine	150mg	Tab	MIN	0.1197
02526387	Mint-Ranitidine	300mg	Tab	MIN	0.2253

(Interchangeable with Zantac – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02522101	Nat-Montelukast	4mg	Chew Tab	NAT	0.2758

(Interchangeable with Singulair – LU)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02527014	NRA-Candesartan	8mg	Tab	NRA	0.2281
02527022	NRA-Candesartan	16mg	Tab	NRA	0.2281
02527030	NRA-Candesartan	32mg	Tab	NRA	0.2281

(Interchangeable with Atacand – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02477645	NRA-Citalopram	20mg	Tab	NRA	0.1332
02477653	NRA-Citalopram	40mg	Tab	NRA	0.1332

(Interchangeable with Celexa – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02522799	PMS-Tofacitinib	5mg	Tab	PMS	5.9897

(Interchangeable with Xeljanz – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02511304	Taro-Tofacitinib	5mg	Tab	TAR	5.9897
02511312	Taro-Tofacitinib	10mg	Tab	TAR	21.1718

(Interchangeable with Xeljanz – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02429322	Teva-Diltiazem XC	180mg	ER Tab	TEV	0.9195
02429330	Teva-Diltiazem XC	240mg	ER Tab	TEV	1.2212
02429349	Teva-Diltiazem XC	300mg	ER Tab	TEV	1.2175
02429357	Teva-Diltiazem XC	360mg	ER Tab	TEV	1.2211

(Interchangeable with Tiazac XC – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02525046	Trandolapril	1mg	Cap	SAI	0.1762
02525054	Trandolapril	2mg	Cap	SAI	0.2025
02525070	Trandolapril	4mg	Cap	SAI	0.2498

(Interchangeable with Mavik – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02526565	Trandolapril	1mg	Cap	SIV	0.1762
02526573	Trandolapril	2mg	Cap	SIV	0.2025
02526581	Trandolapril	4mg	Cap	SIV	0.2498

(Interchangeable with Mavik – GB)

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02518910	GLN-Apremilast	30mg	Tab	GLP	18.7239

(Interchangeable with Otezla)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02528207	Jamp Clonidine	0.025mg	Tab	JPC	0.2713

(Interchangeable with Dixarit)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02530244	Modafinil	100mg	Tab	SAI	0.9293

(Interchangeable with Alertec)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02529076	Moxifloxacin	0.5% w/v	Oph Sol-3mL Pk (Preservative-Free)	SAI	11.2700

(Interchangeable with Vigamox)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02524511	M-Valsartan	40mg	Tab	MAT	0.5823

(Interchangeable with Diovan)

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

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02522128	Nat-Montelukast	5mg	Chew Tab	NAT	1.2077
02522136	Nat-Montelukast	10mg	Tab	NAT	1.7737

(Interchangeable with Singulair)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02489384	NRA-Rizatriptan ODT	10mg	ODT	NRA	11.1150

(Interchangeable with Maxalt RPD)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02489392	NRA-Zolmitriptan	2.5mg	Tab	NRA	6.8600

(Interchangeable with Zomig)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02521733	PMS-Apremilast	30mg	Tab	PMS	18.7238

(Interchangeable with Otezla)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02529084	Sandoz Apremilast	30mg	Tab	SDZ	18.7238

(Interchangeable with Otezla)

Ontario

Revision of Limited Use Criteria

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02419475	Inflectra	100mg/Vial	Inj Pd-Vial Pk	CEH

Limited Use Codes Revised Clinical Criteria

Code 477

Ulcerative Colitis

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. Infliximab 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 regimen is 5mg/kg/dose at 0, 2, and 6 weeks.

The recommended maintenance dosing regimen is 5mg/kg/dose every 8 weeks. (Note: higher doses may be considered in patients who have failed to respond to lower doses.)

Revision to Limited Use Criteria (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., 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.

Exclusion criteria (initial and renewal coverage):

- Combination therapy with another biologic used to treat inflammatory bowel 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 478

Luminal Crohn’s disease

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 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

Revision to Limited Use Criteria (Continued)

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

The recommended induction dosing regimen is 5mg/kg/dose at 0, 2, and 6 weeks.

The recommended maintenance dosing regimen is 5mg/kg/dose every 8 weeks. (Note: higher doses up to 10mg/kg/dose may be considered in patients who have failed to respond to lower doses.)

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.

LU Authorization Period: 1 year

Revision to Limited Use Criteria (Continued)
Code 479

Fistulising Crohn’s disease

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

- 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)

The recommended induction dosing regimen is 5mg/kg/dose at 0, 2, and 6 weeks.

The recommended maintenance dosing regimen is 5mg/kg/dose every 8 weeks. (Note: higher doses up to 10mg/kg/dose may be considered in patients who have failed to respond to lower doses.)

Maintenance/Renewal:

Maintenance therapy is funded for patients who met the initiation criteria and achieve and maintain response to therapy (e.g., partial or complete resolution of fistulae and symptom improvement).

Exclusion criteria (initial and renewal coverage):

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

LU Authorization Period: 1 year

Revision to Limited Use Criteria (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02470373	Renflexis	100mg/Vial	Inj Pd-Vial Pk	SAM

Limited Use Codes Revised Clinical Criteria

Code 545

Ulcerative Colitis

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. Infliximab 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 regimen is 5mg/kg/dose at 0, 2, and 6 weeks.

The recommended maintenance dosing regimen is 5mg/kg/dose every 8 weeks. (Note: higher doses may be considered in patients who have failed to respond to lower doses.)

Maintenance/Renewal:

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

Revision to Limited Use Criteria (Continued)

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.

Exclusion criteria (initial and renewal coverage):

- Combination therapy with another biologic used to treat inflammatory bowel 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 546

Luminal Crohn’s disease

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

Revision to Limited Use Criteria (Continued)

The recommended induction dosing regimen is 5mg/kg/dose at 0, 2, and 6 weeks.

The recommended maintenance dosing regimen is 5mg/kg/dose every 8 weeks. (Note: higher doses up to 10mg/kg/dose may be considered in patients who have failed to respond to lower doses.)

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.

LU Authorization Period: 1 year

Code 547

Fistulising Crohn’s disease

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

- 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)

The recommended induction dosing regimen is 5mg/kg/dose at 0, 2, and 6 weeks.

Revision to Limited Use Criteria (Continued)

The recommended maintenance dosing regimen is 5mg/kg/dose every 8 weeks. (Note: higher doses up to 10mg/kg/dose may be considered in patients who have failed to respond to lower doses.)

Maintenance/Renewal:

Maintenance therapy is funded for patients who met the initiation criteria and achieve and maintain response to therapy (e.g., partial or complete resolution of fistulae and symptom improvement).

Exclusion criteria (initial and renewal coverage):

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

LU Authorization Period: 1 year

Revision to Limited Use Criteria (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02511045	Abrilada	40mg/0.8mL	Inj Sol-0.8mL Pref Pen (Preservative-Free)	PFI
02511053	Abrilada	40mg/0.8mL	Inj Sol-0.8mL Pref Syr (Preservative-Free)	PFI
02459310	Amgevita	20mg/0.4mL	Inj Sol-0.4mL Pref Syr (Preservative-Free)	AMG
02459302	Amgevita	40mg/0.8mL	Inj Sol-0.8mL Pref Autoinj (Preservative-Free)	AMG
02459299	Amgevita	40mg/0.8mL	Inj Sol-0.8mL Pref Syr (Preservative-Free)	AMG
02473097	Hadlima	40mg/0.8mL	Inj Sol-0.8mL Pref Syr (Preservative-Free)	SAM
02473100	Hadlima PushTouch	40mg/0.8mL	Inj Sol-0.8mL Pref Autoinj (Preservative-Free)	SAM
02502380	Hulio	20mg/0.4mL	Inj Sol-0.4mL Pref Syr (Preservative-Free)	BGP
02502402	Hulio	40mg/0.8mL	Inj Sol-0.8mL Pref Pen (Preservative-Free)	BGP
02502399	Hulio	40mg/0.8mL	Inj Sol-0.8mL Pref Syr (Preservative-Free)	BGP
02505258	Hyrimoz	20mg/0.4mL	Inj Sol-0.4mL Pref Syr (Preservative-Free)	SDZ
02492156	Hyrimoz	40mg/0.8mL	Inj Sol-0.8mL Pref Autoinj (Preservative-Free)	SDZ
02492164	Hyrimoz	40mg/0.8mL	Inj Sol-0.8mL Pref Syr (Preservative-Free)	SDZ
02502674	Idacio	40mg/0.8mL	Inj Sol-0.8mL Pref Pen (Preservative-Free)	FKC
02502682	Idacio	40mg/0.8mL	Inj Sol-0.8mL Pref Syr (Preservative-Free)	FKC
02523949	Simlandi	40mg/0.4mL	Inj Sol-0.4mL Pref Syr (Preservative-Free)	JPC
02523957	Simlandi	40mg/0.4mL	Inj Sol-0.4mL Pref Autoinj Syr (Preservative-Free)	JPC
02523965	Simlandi	80mg/0.8mL	Inj Sol-0.8mL Pref Syr (Preservative-Free)	JPC
02523779	Yuflyma	40mg/0.4mL	Inj Sol-0.4mL Pref Autoinj Pen (Preservative-Free)	CEH
02523760	Yuflyma	40mg/0.4mL	Inj Sol-0.4mL Pref Syr (Preservative-Free)	CEH

Revision to Limited Use Criteria (Continued)
Limited Use Codes Revised Clinical Criteria

Code 604

Luminal Crohn’s disease

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

The recommended induction dosing regimen is 160mg at week 0, followed by 80mg at week 2.

The recommended maintenance dosing regimen is up to 40mg every 2 weeks. (Note: higher doses may be considered in patients who have failed to respond to lower doses.)

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.

Revision to Limited Use Criteria (Continued)

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.

LU Authorization Period: 1 year

Code 605

Fistulising Crohn's disease

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

B. Harvey Bradshaw Index (HBI) score greater than or equal to 7 (or other validated disease activity score confirming moderate to severe disease)

The recommended induction dosing regimen is 160mg at week 0, followed by 80mg at week 2.

The recommended maintenance dosing regimen is up to 40mg every 2 weeks. (Note: higher doses may be considered in patients who have failed to respond to lower doses.)

Maintenance/Renewal:

Maintenance therapy is funded for patients who met the initiation criteria and achieve and maintain response to therapy (e.g., partial or complete resolution of fistulae and symptom improvement).

Revision to Limited Use Criteria (Continued)

Exclusion criteria (initial and renewal coverage):

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

LU Authorization Period: 1 year

Code 606

Ulcerative Colitis

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. Adalimumab 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 regimen is up to 160mg at week 0, followed by up to 80mg at week 2.

The recommended maintenance dosing regimen is up to 40mg every 2 weeks. (Note: higher doses may be considered in patients who have failed to respond to lower doses.)

Revision to Limited Use Criteria (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., 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.

Exclusion criteria (initial and renewal coverage):

- Combination therapy with another biologic used to treat inflammatory bowel 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

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02496933	Avsola	100mg/Vial	Pd for Sol-Vial Pk	AMG

Limited Use Codes Revised Clinical Criteria

Code 596

Ulcerative Colitis

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

Revision to Limited Use Criteria (Continued)

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. Infliximab 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 regimen is 5mg/kg/dose at 0, 2, and 6 weeks.

The recommended maintenance dosing regimen is 5mg/kg/dose every 8 weeks. (Note: higher doses may be considered in patients who have failed to respond to lower doses.)

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.

Exclusion criteria (initial and renewal coverage):

- Combination therapy with another biologic used to treat inflammatory bowel 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

Revision to Limited Use Criteria (Continued)

Code 597

Luminal Crohn’s disease

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

The recommended induction dosing regimen is 5mg/kg/dose at 0, 2, and 6 weeks.

The recommended maintenance dosing regimen is 5mg/kg/dose every 8 weeks. (Note: higher doses up to 10mg/kg/dose may be considered in patients who have failed to respond to lower doses.)

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.

Revision to Limited Use Criteria (Continued)

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.

LU Authorization Period: 1 year

Code 598

Fistulising Crohn's disease

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

- 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)

The recommended induction dosing regimen is 5mg/kg/dose at 0, 2, and 6 weeks.

The recommended maintenance dosing regimen is 5mg/kg/dose every 8 weeks. (Note: higher doses up to 10mg/kg/dose may be considered in patients who have failed to respond to lower doses.)

Maintenance/Renewal:

Maintenance therapy is funded for patients who met the initiation criteria and achieve and maintain response to therapy (e.g., partial or complete resolution of fistulae and symptom improvement).

Exclusion criteria (initial and renewal coverage):

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

LU Authorization Period: 1 year

Ontario

Removal of Therapeutic Note

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
09857268	Mirapex	0.25mg	Tab	BOE
02292378	Apo-Pramipexole	0.25mg	Tab	APX
02424061	Auro-Pramipexole	0.25mg	Tab	AUR
02297302	Co Pramipexole	0.25mg	Tab	COB
02367602	Pramipexole	0.25mg	Tab	SAI
02309122	Pramipexole	0.25mg	Tab	SIV
02315262	Sandoz Pramipexole	0.25mg	Tab	SDZ

Therapeutic Note to be removed:

NOTE: Mirapex is indicated for both the symptomatic treatment of idiopathic Parkinson's Disease and moderate to severe idiopathic Restless Legs Syndrome under the manufacturer's Drug Identification Number (DIN). Mirapex has also been assigned a Product Identification Number (PIN) for the indication of Parkinson's Disease specifically. Apo-Pramipexole, Auro-Pramipexole, Novo-Pramipexole, Sandoz Pramipexole, Co Pramipexole and Mylan-Pramipexole products are interchangeable with Mirapex for the treatment of Parkinson's Disease.

All generic pramipexole 0.25mg Tab products are now in the same interchangeable category with Mirapex 0.25mg Tab DIN 02237145. The Mirapex PIN 09857268 is delisted.

Ontario

Product Brand Name Changes

DIN/PIN	Current Product Name	New Product Name	MFR	Strength	Dosage Form
02296349	Act Ondansetron	Teva-Ondansetron	TEV	4mg	Tab
02296357	Act Ondansetron	Teva-Ondansetron	TEV	8mg	Tab

Ontario

Product Brand and Manufacturer Name Changes

DIN/PIN	Current Product Name	Current Mfr	New Product Name	New Mfr	Strength	Dosage Form
02297302	Co Pramipexole	COB	Act Pramipexole	TEV	0.25mg	Tab
02297310	Co Pramipexole	COB	Act Pramipexole	TEV	0.5mg	Tab
02297329	Co Pramipexole	COB	Act Pramipexole	TEV	1mg	Tab
02297337	Co Pramipexole	COB	Act Pramipexole	TEV	1.5mg	Tab

Ontario

Drug Benefit Price (DBP) Changes

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP/Unit Price
02441934	Act Methylphenidate ER	18mg	SR Tab	TEV	1.0493
02441942	Act Methylphenidate ER	27mg	SR Tab	TEV	1.2109
02441950	Act Methylphenidate ER	36mg	SR Tab	TEV	1.3726
02441969	Act Methylphenidate ER	54mg	SR Tab	TEV	1.6958
02244394	Apo-Cefuroxime	500mg	Tab	APX	1.6616
02452731	Apo-Methylphenidate ER	18mg	SR Tab	APX	1.0493
02452758	Apo-Methylphenidate ER	27mg	SR Tab	APX	1.2109
02452766	Apo-Methylphenidate ER	36mg	SR Tab	APX	1.3726
02330377	Apo-Methylphenidate ER	54mg	SR Tab	APX	1.6958
02426552	Apo-Linezolid	600mg	Tab	APX	19.3041
02344831	Auro-Cefuroxime	500mg	Tab	AUR	1.6616
02247732	Concerta	18mg	SR Tab	JAN	3.0171
02250241	Concerta	27mg	SR Tab	JAN	3.4819
02247733	Concerta	36mg	SR Tab	JAN	3.9468
02247734	Concerta	54mg	SR Tab	JAN	4.8761
00263818	Cotazym	8000 & 30000 & 30000 USP Units	Cap	ORG	0.2520
00502790	Cotazym ECS 8	8000 & 30000 & 30000 USP Units	Ent Microsph Cap	ORG	0.4549
00821373	Cotazym ECS 20	20000 & 55000 & 55000 USP Units	Ent Microsph Cap	ORG	1.1928
02298791	Emend	80mg	Cap	MEK	35.3082
02298805	Emend	125mg	Cap	MEK	34.9776
02298813	Emend Tri-Pack	125mg & 80mg	Cap	MEK	105.9246

Drug Benefit Price (DBP) Changes (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP/Unit Price
02042487	Marvelon 21	0.15mg & 0.03mg	Tab-21 Pk	ORG	20.1010
02042479	Marvelon 28	0.15mg & 0.03mg	Tab-28 Pk	ORG	20.1010
02240521	Maxalt	10mg	Tab	OCI	21.4865
02240518	Maxalt RPD	5mg	Orally Disintegrating Tab	OCI	21.4865
02240519	Maxalt RPD	10mg	Orally Disintegrating Tab	OCI	21.4865
02529769	M-Ticagrelor	90mg	Tab	MAT	0.3960
02243796	Pariet	10mg	Tab	JAN	1.4651
02243797	Pariet	20mg	Tab	JAN	2.9301
02236950	Risperdal	1mg/mL	O/L	JAN	1.5430/mL
02255707	Risperdal Consta	25mg	Pd for Inj-Vial Pk	JAN	191.1500
02255723	Risperdal Consta	37.5mg	Pd for Inj-Vial Pk	JAN	286.7100
02255758	Risperdal Consta	50mg	Pd for Inj-Vial Pk	JAN	382.2800
02422689	Sandoz Linezolid	600mg	Tab	SDZ	19.3041
02243602	Singulair	4mg	Chew Tab	OCI	1.5982
02231347	Sporanox	10mg/mL	Oral Sol	JAN	1.1164/mL
02047454	Sporanox	100mg	Cap	JAN	5.9810
02492598	Taro-Ticagrelor	90mg	Tab	TAR	0.3960
02230893	Topamax	25mg	Tab	JNO	2.0797
02230894	Topamax	100mg	Tab	JNO	3.9000
02230896	Topamax	200mg	Tab	JNO	5.7585
02239907	Topamax Sprinkle	15mg	Sprinkle Cap	JNO	1.9800
02239908	Topamax Sprinkle	25mg	Sprinkle Cap	JNO	2.0700
02244981	Tracleer	62.5mg	Tab	JAN	78.4500
02244982	Tracleer	125mg	Tab	JAN	78.4500
00556734	Vermox	100mg	Tab	JAN	9.2650
02250519	Zavesca	100mg	Cap	ACT	128.9600
02361752	Zenhale	100mcg & 5mcg Metered Dose	Inh-120 Dose Pk	OCI	111.3000
02361760	Zenhale	200mcg & 5mcg Metered Dose	Inh-120 Dose Pk	OCI	134.8600

Discontinued Products

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

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
00585092	Depo-Provera	150mg/mL	Inj	PFI
01931563	Gastrolyte		Oral Pd-1 Sach Pk	SAV
09858001	InspiraChamber			INS
09858002	InspiraChamber + Mask Small			INS
09858003	InspiraChamber + Mask Medium			INS
09858004	InspiraChamber + Mask Large			INS
02513447	Riabni	10mg/mL	Inj Sol-Vial (Preservative-Free)	AMG
02353040	Ropinirole	0.25mg	Tab	SAI
02353059	Ropinirole	1mg	Tab	SAI
02303396	Sandoz Metoprolol SR	100mg	LA Tab	SDZ
02303418	Sandoz Metoprolol SR	200mg	LA Tab	SDZ

Ontario

Delisted Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02413736	PMS-Methylphenidate ER	27mg	SR Tab	PMS
02413744	PMS-Methylphenidate ER	36mg	SR Tab	PMS
00021261	Teva-Chloroquine	250mg	Tab	TEV