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# Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – September 2020
Effective September 30, 2020

Drug Programs Policy and Strategy Branch
Drugs and Devices Division
Ministry of Health

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# New Single Source Products

| DIN/PIN | Brand Name | Strength | Dosage Form | Generic Name | Mfr | DBP |
|---|---|---|---|---|---|---|
| 02485877 | Envarsus PA | 0.75mg | ER Tab | TACROLIMUS | EVL | 2.0406 |
| 02485885 | Envarsus PA | 1mg | ER Tab | TACROLIMUS | EVL | 2.5575 |
| 02485893 | Envarsus PA | 4mg | ER Tab | TACROLIMUS | EVL | 10.2300 |

## Reason For Use Code and Clinical Criteria

## Code 590

For the prophylaxis of organ rejection in allogenic kidney or liver transplant adult patients in combination with other immunosuppressants.

LU Authorization Period: Indefinite

| DIN/PIN | Brand Name | Strength | Dosage Form | Generic Name | Mfr | DBP |
|---|---|---|---|---|---|---|
| 02483459 | Stramucin | 2% w/w | Cr | MUPIROCIN CALCIUM | GLP | 1.3000/g |

# New Single Source Products (Continued)

| DIN/PIN | Brand Name | Strength | Dosage Form | Generic Name | Mfr | DBP |
|---|---|---|---|---|---|---|
| 02480786 | Xeljanz | 10mg | Tab | TOFACITINIB CITRATE | PFI | 42.3436 |

Xeljanz 5mg Tab (DIN 02423898) will have the same LU Code 589 and criteria added as with the 10mg strength.

## Reason For Use Code and Clinical Criteria

## Code 589

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)
    OR
    d. 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)

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

# New Single Source Products (Continued)

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

The recommended dosing regimen for induction is 10mg twice daily for at least 8 weeks.

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 Xeljanz or be off corticosteroids after the first year of treatment.

The recommended dosing regimen is 5mg twice daily.

Depending on therapeutic response; 10mg twice daily may also be used for maintenance in some patients. However, the lowest effective dose possible should be used for maintenance therapy to minimize adverse effects.

LU Authorization Period: 1 year

| DIN/PIN | Brand Name | Strength | Dosage Form | Generic Name | Mfr | DBP |
|---|---|---|---|---|---|---|
| 02493373 | Toujeo DoubleSTAR | 300U/mL | Inj Sol-3mL Pref Pen | INSULIN GLARGINE | SAC | 52.8666/ Pref Pen |

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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 |
|---|---|---|---|---|---|
| 02476517 | NRA-Atorvastatin | 10mg | Tab | NRA | 0.1743 |
| 02476525 | NRA-Atorvastatin | 20mg | Tab | NRA | 0.2179 |
| 02476533 | NRA-Atorvastatin | 40mg | Tab | NRA | 0.2342 |
| 02476541 | NRA-Atorvastatin | 80mg | Tab | NRA | 0.2342 |

(Interchangeable with Lipitor – GB)

| DIN/PIN | Product Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02486172 | NRA-Ramipril | 2.5mg | Cap | NRA | 0.0817 |
| 02486180 | NRA-Ramipril | 5mg | Cap | NRA | 0.0817 |
| 02486199 | NRA-Ramipril | 10mg | Cap | NRA | 0.1034 |

(Interchangeable with Altace – GB)

| DIN/PIN | Product Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02477483 | NRA-Rosuvastatin | 5mg | Tab | NRA | 0.1284 |
| 02477491 | NRA-Rosuvastatin | 10mg | Tab | NRA | 0.1354 |
| 02477505 | NRA-Rosuvastatin | 20mg | Tab | NRA | 0.1692 |

(Interchangeable with Crestor – GB)

# New Multi-Source Products (Continued)

| DIN/PIN | Product Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02388944 | Telmisartan | 40mg | Tab | SAI | 0.2161 |
| 02388952 | Telmisartan | 80mg | Tab | SAI | 0.2161 |

(Interchangeable with Micardis – GB)

| DIN/PIN | Product Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02395355 | Telmisartan/HCTZ | 80mg & 12.5mg | Tab | SAI | 0.2098 |
| 02395363 | Telmisartan/HCTZ | 80mg & 25mg | Tab | SAI | 0.2098 |

(Interchangeable with Micardis Plus – GB)

| DIN/PIN | Product Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02366959 | Valsartan | 80mg | Tab | SAI | 0.2159 |
| 02366967 | Valsartan | 160mg | Tab | SAI | 0.2159 |
| 02366975 | Valsartan | 320mg | Tab | SAI | 0.2098 |

(Interchangeable with Diovan – GB)

| DIN/PIN | Product Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02388960 | Losartan HCT | 50mg & 12.5mg | Tab | SIV | 0.3147 |
| 02388979 | Losartan HCT | 100mg & 12.5mg | Tab | SIV | 0.3082 |

(Interchangeable with Hyzaar – GB)

# New Multi-Source Products (Continued)

| DIN/PIN | Product Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02388987 | Losartan HCT | 100mg & 25mg | Tab | SIV | 0.3147 |

(Interchangeable with Hyzaar DS – GB)

| DIN/PIN | Product Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02493780 | Acarbose Tablets | 50mg | Tab | STR | 0.1348 |
| 02493799 | Acarbose Tablets | 100mg | Tab | STR | 0.1866 |

(Interchangeable with Glucobay – LU)

| DIN/PIN | Product Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02489635 | Dorzolamide and Timolol Eye Drops BP | 20mg/mL & 5mg/mL | Oph Sol (With Preservative) | TCI | 2.0951/mL |

(Interchangeable with Cosopt – LU)

| DIN/PIN | Product Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02489368 | Latanoprost and Timolol Ophthalmic Solution | 50mcg/mL & 5mg/mL | Oph Sol-2.5mL Pk (With Preservative) | TCI | 11.0670 |

(Interchangeable with Xalacom – LU)

| DIN/PIN | Product Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02489570 | Latanoprost Ophthalmic Solution | 50mcg/mL | Oph Sol-2.5mL Pk (With Preservative) | TCI | 9.5830 |

(Interchangeable with Xalatan – LU)

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# New Off-Formulary Interchangeable (OFI) Products

| DIN/PIN | Brand Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02494337 | Teva-Liothyronine | 5mcg | Tab | TEV | 1.1587 |
| 02494345 | Teva-Liothyronine | 25mcg | Tab | TEV | 1.2595 |

(Interchangeable with Cytomel)

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# Transition from Off-Formulary Interchangeable (OFI) Products to General Benefit

| DIN/PIN | Brand Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 02248624 | Faslodex | 50mg/mL | Inj Sol | AZC | 116.5790/mL |
| 02483610 | Fulvestrant Injection | 50mg/mL | Inj Sol | SDZ | 58.2895/mL |
| 02460130 | Teva-Fulvestrant Injection | 50mg/mL | Inj Sol | TEV | 58.2895/mL |

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# Addition of Reason For Use Code

| DIN/PIN | Brand Name | Strength | Dosage Form | Mfr |
|---|---|---|---|---|
| 02478382 | Truxima | 100mg/10mL | Inj Sol-10mL Vial Pk | CEH |
| 02478390 | Truxima | 500mg/50mL | Inj Sol-50mL Vial Pk | CEH |

## Reason For Use Code and Clinical Criteria

## Code 587

Rituximab is used in combination with glucocorticoids for the induction of remission in patients with severely active Granulomatosis with Polyangiitis [(GPA), also known as Wegener's Granulomatosis (WG)] OR microscopic polyangiitis (MPA), for Patients who meet all of the following criteria:

1. The patient must have severe active disease that is life- or organ-threatening as supported by laboratory and/or imaging reports.

   AND

2. There is a positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic autoantibodies) or myeloperoxidase-ANCA.

   AND

3. Cyclophosphamide cannot be used by the Patient for ONE of the following reasons:
   a. The patient has failed a minimum of six IV pulses of cyclophosphamide; OR
   b. The patient has failed three months of oral cyclophosphamide therapy; OR
   c. The patient has a severe intolerance or an allergy to cyclophosphamide; OR
   d. Cyclophosphamide is contraindicated; OR
   e. The patient has received a cumulative lifetime dose of at least 25g of cyclophosphamide; OR
   f. The patient wishes to preserve ovarian/testicular function for fertility.

4. The request is from a prescriber experienced in the diagnosis and management of GPA, MPA, and vasculitis.

Exclusion criteria:

The patient should not have received a course of rituximab in the prior 6 months.

The recommended dosing regimen for the initial treatment would be a once weekly infusion dosed at 375 milligrams per square metre x 4 weeks.

# Addition of Reason For Use Code (Continued)

Case-by-case considerations for patients not meeting the LU criteria may be considered through the Exceptional Access Program.

LU Authorization Period: 1 month (1 treatment course)

## Code 588

Rituximab (Truxima) treatment will be used for Patients with severely active Granulomatosis with Polyangiitis [(GPA), also known as Wegener's Granulomatosis (WG)] OR microscopic polyangiitis (MPA) who have achieved disease remission. Patient must meet all of the following criteria:

1. The Patient must have severe active disease that is life- or organ-threatening as supported by laboratory and/or imaging reports.
2. There is a positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic autoantibodies) or myeloperoxidase-ANCA. A copy of the laboratory report must be provided.
3. Stabilization of the condition with induction doses of cyclophosphamide (injectable or oral doses are acceptable) and a glucocorticoid as combination over 4 to 6 months until disease remission prior to initiation of rituximab.
4. The request is from a prescriber experienced in the diagnosis and management of GPA, MPA, and vasculitis.

Exclusion criteria:

The Patient should not have received a dose of rituximab in the prior 6 months. Doses of rituximab administered at intervals more frequently than every 6 months are not funded.

The recommended dosing regimen: A fixed dose regimen of rituximab of 500mg IV every 6 months.

Case-by-case considerations for Patients not meeting the LU criteria may be considered through the Exceptional Access Program.

LU Authorization Period: 1 year

# Addition of Reason For Use Code (Continued)

| DIN/PIN | Brand Name | Strength | Dosage Form | Mfr |
|---|---|---|---|---|
| 02462877 | Erelzi | 25mg/0.5mL | Inj Sol-0.5mL Pref Syr Pk | SDZ |
| 02462850 | Erelzi | 50mg/mL | Inj Sol-1mL Prefilled SensoReady Pen Pk | SDZ |
| 02462869 | Erelzi | 50mg/mL | Inj Sol-1mL Pref Syr Pk | SDZ |

## Reason For Use Code and Clinical Criteria

## Code 591

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.

# Addition of Reason For Use Code (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

Approvals will only allow for standard dosing for Erelzi (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.

LU Authorization Period: 1 year

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# Temporary Benefits

| DIN/PIN | Brand Name | Strength | Dosage Form | Generic Name | Mfr | DBP |
|---|---|---|---|---|---|---|
| 09858127 | Sublocade | 100mg/0.5mL | Inj Sol-0.5mL Pref Syr | BUPRENORPHINE | IND | 550.0000/Pref Syr |
| 09858128 | Sublocade | 300mg/1.5mL | Inj Sol-1.5mL Pref Syr | BUPRENORPHINE | IND | 550.0000/Pref Syr |

## Clinical Criteria:

For the management of moderate to severe opioid use disorder as a part of a complete treatment plan that includes counselling and psychosocial support in adult patients who meet the following criteria:

- The patient has been induced and is stabilized on an equivalent of 8mg to 24mg per day of transmucosal buprenorphine for a minimum of seven days; AND
- The patient is under the care of a health care provider with experience in the diagnosis and management of opioid use disorder; AND
- Each dose is administered subcutaneously in the abdominal region by a certified healthcare provider who has received instruction and training.

Recommended dose: 300mg/month for two months, followed by a maintenance dose of 100mg/month. Maintenance dose may be increased to 300mg/month only if patient does not demonstrate satisfactory clinical response.

NOTE: In clinical trials, the 300mg/month maintenance dose did not provide additional efficacy as compared to the 100mg/month dose and was associated with a higher incidence of adverse events and study discontinuations. A minimum of 26 days is required between consecutive doses.

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# Drug Benefit Price (DBP) Changes

| DIN/PIN | Brand Name | Strength | Dosage Form | Mfr | DBP |
|---|---|---|---|---|---|
| 00335134 | Perphenazine | 2mg | Tab | AAP | 0.0668 |
| 00335126 | Perphenazine | 4mg | Tab | AAP | 0.0808 |
| 00335118 | Perphenazine | 8mg | Tab | AAP | 0.0888 |
| 00335096 | Perphenazine | 16mg | Tab | AAP | 0.1359 |
| 02083523 | Bezalip | 400mg | SR Tab | AGP | 2.4443 |
| 02070847 | Soriatane | 10mg | Cap | AGP | 2.7227 |
| 02070863 | Soriatane | 25mg | Cap | AGP | 4.7817 |
| 02478382 | Truxima | 100mg/10mL | Inj Sol-10mL Vial Pk | CEH | 297.0000 |
| 02478390 | Truxima | 500mg/50mL | Inj Sol-50mL Vial Pk | CEH | 1485.0000 |
| 02494078 | Mar-Acarbose | 50mg | Tab | MAR | 0.1348 |
| 02494086 | Mar-Acarbose | 100mg | Tab | MAR | 0.1866 |
| 02418282 | Ultibro Breezhaler | 110mcg & 50mcg | Inh Pd-Cap | NOV | 2.5830 |
| 00568627 | Viskazide 10/25 | 10mg & 25mg | Tab | NOV | 1.1557 |
| 00568635 | Viskazide 10/50 | 10mg & 50mg | Tab | NOV | 1.1557 |
| 00716871 | Nyaderm | 100000U/g | Cr | TAR | 0.0960 |

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# Discontinued 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 |
| 02476630 | Apo-HYDROmorphone CR | 6mg | CR Cap | APX |
| 02476649 | Apo-HYDROmorphone CR | 9mg | CR Cap | APX |
| 02476657 | Apo-HYDROmorphone CR | 12mg | CR Cap | APX |
| 02476665 | Apo-HYDROmorphone CR | 18mg | 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 |
| 02247439 | Sandoz Bisoprolol | 5mg | Tab | SDZ |
| 02247440 | Sandoz Bisoprolol | 10mg | Tab | SDZ |
| 02410818 | Jetrea | 2.5mg/mL | Inj Sol-0.2mL Vial Pk (Preservative-Free) | THO |

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# Delisted Products

| DIN/PIN | Brand Name | Strength | Dosage Form | Mfr |
|---|---|---|---|---|
| 02404990 | Auro-Anastrozole | 1mg | Tab | AUR |
| 02404400 | Auro-Letrozole | 2.5mg | Tab | AUR |
| 02231675* | Combivent UDV | 500mcg/2.5mg/2.5mL | Inh Sol-2.5mL Amp Pk | BOE |
| 02349124 | Effient | 10mg | Tab | LIL |
| 02229552 | Diarr-eze | 2mg | Caplet | PMS |
| 02300079 | PMS-Enalapril | 2.5mg | Tab | PMS |
| 02300087 | PMS-Enalapril | 5mg | Tab | PMS |
| 02300095 | PMS-Enalapril | 10mg | Tab | PMS |
| 02300109 | PMS-Enalapril | 20mg | Tab | PMS |
| 02303949 | PMS-Escitalopram | 10mg | Tab | PMS |
| 02303965 | PMS-Escitalopram | 20mg | Tab | PMS |
| 02245480 | PMS-Flavoxate | 200mg | Tab | PMS |
| 02282348 | PMS-Fluconazole | 150mg | Cap | PMS |
| 02423944 | PMS-Olanzapine ODT | 20mg | Rapid Dissolve Tab | PMS |
| 02310260 | PMS-Omeprazole DR Tab | 20mg | Tab | PMS |

# Delisted Products (Continued)

| DIN/PIN | Brand Name | Strength | Dosage Form | Mfr |
|---|---|---|---|---|
| 02231536 | PMS-Pindolol | 5mg | Tab | PMS |
| 02231537 | PMS-Pindolol | 10mg | Tab | PMS |
| 02154463 | PMS-Piroxicam | 20mg | Sup | PMS |
| 02290111 | PMS-Pramipexole | 0.25mg | Tab | PMS |
| 02290138 | PMS-Pramipexole | 0.5mg | Tab | PMS |
| 02290146 | PMS-Pramipexole | 1mg | Tab | PMS |
| 02290154 | PMS-Pramipexole | 1.5mg | Tab | PMS |
| 02342146 | PMS-Ramipril-HCTZ | 5mg & 12.5mg | Tab | PMS |
| 02291789 | PMS-Risperidone ODT | 1mg | ODT | PMS |
| 02291797 | PMS-Risperidone ODT | 2mg | ODT | PMS |
| 02370697 | PMS-Risperidone ODT | 3mg | ODT | PMS |
| 02370700 | PMS-Risperidone ODT | 4mg | ODT | PMS |
| 02312999 | PMS-Valsartan | 40mg | Tab | PMS |
| 02313006 | PMS-Valsartan | 80mg | Tab | PMS |
| 02192284* | Cyclocort | 0.1% | Cr | STI |

*Remain on the Formulary as Not-a-Benefit (NAB) to serve as the reference product in the interchangeable group.