

# Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 42

Summary of Changes - September 2014

Effective September 25, 2014

Ministry of Health and Long-Term Care

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# New Single Source Products

| DIN/PIN  | PRODUCT NAME                    | GENERIC NAME | MFR | DBP     |
|----------|---------------------------------|--------------|-----|---------|
| 02298813 | Emend Tri-Pack 125mg & 80mg Cap | APREPITANT   | MEK | 94.6400 |

## Reason For Use Code and Clinical Criteria

### Code 452

In combination with a 5HT3 receptor antagonist and dexamethasone for highly emetogenic chemotherapy (HEC) regimens:

- Cisplatin-based chemotherapy where a single daily dose is greater than or equal to 70 mg per meter squared
- Cisplatin and cyclophosphamide combinations where the single daily dose is greater than or equal to 50mg per meter squared
- Cisplatin (any dose) given for 3 to 5 consecutive days
- Non-cisplatin based highly emetogenic chemotherapy (such as those containing anthracycline greater than or equal to 60mg per meter squared plus cyclophosphamide)

Dosage: Recommend aprepitant 125mg orally on Day 1 of HEC followed by 80mg orally on Days 2 to 3 post-chemotherapy for each cycle.

LU Authorization Period: 1 year.

### Code 453

For patients receiving moderately emetogenic chemotherapy (MEC) regimens AND who have had inadequate symptom control using a 5HT3 antagonist and dexamethasone in a previous cycle.

Dosage: Recommend aprepitant 125mg orally on Day 1 of MEC followed by 80mg orally on Days 2 to 3 post-chemotherapy for each cycle.

LU Authorization Period: 1 year.

# New Multi-Source Products

| DIN/PIN  | BRAND NAME         | STRENGTH | DOSAGE FORM | MFR | DBP    |
|----------|--------------------|----------|-------------|-----|--------|
| 02422646 | Abbott-Rabeprazole | 20mg     | Tab         | ABB | 0.2408 |

*(Interchangeable with Pariet)*

| DIN/PIN  | BRAND NAME                 | STRENGTH | DOSAGE FORM | MFR | DBP    |
|----------|----------------------------|----------|-------------|-----|--------|
| 02412691 | Act Dutasteride            | 0.5mg    | Cap         | ACV | 0.4205 |
| 02404206 | Apo-Dutasteride            | 0.5mg    | Cap         | APX | 0.4205 |
| 02393220 | PMS-Dutasteride            | 0.5mg    | Cap         | PMS | 0.4205 |
| 02424444 | Sandoz Dutasteride Capsule | 0.5mg    | Cap         | SDZ | 0.4205 |
| 02408287 | Teva-Dutasteride           | 0.5mg    | Cap         | TEV | 0.4205 |

*(Interchangeable with Avodart)*

## Reason For Use Code and Clinical Criteria

### Code 384

For use in combination with an alpha blocker for the treatment of men with symptomatic\* Benign Prostatic Hyperplasia.

LU Authorization Period: Indefinite.

### Code 385

For monotherapy, as a second line agent in patients with symptomatic\* Benign Prostatic Hyperplasia following treatment failure or intolerance to an alpha blocker.

\* Symptomatic is defined as having moderate (about half the time) to severe (almost always) symptoms related to the prostate in at least 4 of the following domains:

1. feeling of incomplete emptying of the bladder after voiding
2. needing to urinate again less than 2 hours after previous void
3. stopping and starting urine several times while voiding
4. difficulty postponing urination
5. weak urinary stream
6. pushing or straining to begin voiding
7. the need to get up to void at least 3 times in the night.

LU Authorization Period: Indefinite.

### New Multi-Source Products (Cont'd...)

| DIN/PIN  | BRAND NAME          | STRENGTH | DOSAGE FORM | MFR | DBP    |
|----------|---------------------|----------|-------------|-----|--------|
| 02425157 | Auro-Galantamine ER | 8mg      | ER Cap      | AUR | 1.2465 |
| 02425165 | Auro-Galantamine ER | 16mg     | ER Cap      | AUR | 1.2465 |
| 02425173 | Auro-Galantamine ER | 24mg     | ER Cap      | AUR | 1.2465 |

*(Interchangeable with Reminyl ER)*

### Reason For Use Code and Clinical Criteria

#### Code 347

Initial Trial: For patients with mild to moderate Alzheimer's Disease (Mini-Mental State Exam [MMSE] 10-26). Patients will be reimbursed for a period of up to 3 months after which continued treatment must be reassessed.

Network note: Maximum duration 3 months.

LU Authorization Period: 1 year.

#### Code 348

Continuation: Further reimbursement will be made available to those patients whose disease has not progressed/deteriorated while on this drug. Patients must continue to have a MMSE score of 10-26.

LU Authorization Period: 1 year.

## New Multi-Source Products (Cont'd...)

| DIN/PIN                              | BRAND NAME     | STRENGTH | DOSAGE FORM | MFR | DBP    |
|--------------------------------------|----------------|----------|-------------|-----|--------|
| 02424967                             | Septa-Losartan | 25mg     | Tab         | SET | 0.3147 |
| 02424975                             | Septa-Losartan | 50mg     | Tab         | SET | 0.3147 |
| 02424983                             | Septa-Losartan | 100mg    | Tab         | SET | 0.3147 |
| <i>(Interchangeable with Cozaar)</i> |                |          |             |     |        |

| DIN/PIN                                | BRAND NAME          | STRENGTH | DOSAGE FORM | MFR | DBP    |
|----------------------------------------|---------------------|----------|-------------|-----|--------|
| 02407485                               | Telmisartan Tablets | 40mg     | Tab         | ACH | 0.2824 |
| 02407493                               | Telmisartan Tablets | 80mg     | Tab         | ACH | 0.2824 |
| <i>(Interchangeable with Micardis)</i> |                     |          |             |     |        |

| DIN/PIN                                     | BRAND NAME                                  | STRENGTH      | DOSAGE FORM | MFR | DBP    |
|---------------------------------------------|---------------------------------------------|---------------|-------------|-----|--------|
| 02419114                                    | Telmisartan and Hydrochlorothiazide Tablets | 80mg & 12.5mg | Tab         | ACH | 0.2824 |
| 02419122                                    | Telmisartan and Hydrochlorothiazide Tablets | 80mg & 25mg   | Tab         | ACH | 0.2824 |
| <i>(Interchangeable with Micardis Plus)</i> |                                             |               |             |     |        |

## New Multi-Source Products (Cont'd...)

| DIN/PIN                               | BRAND NAME                | STRENGTH  | DOSAGE FORM      | MFR | DBP      |
|---------------------------------------|---------------------------|-----------|------------------|-----|----------|
| 02422433                              | Zoledronic Acid Injection | 5mg/100mL | Inj Sol-100mL Pk | DRR | 335.4000 |
| <i>(Interchangeable with Aclasta)</i> |                           |           |                  |     |          |

### Reason For Use Code and Clinical Criteria

#### Code 319

For the treatment of Paget's disease.

LU Authorization Period: Indefinite.

#### Code 436

For the treatment of osteoporosis in postmenopausal women who would otherwise be eligible for funding for oral bisphosphonates, but for whom bisphosphonates are contraindicated due to abnormalities of the esophagus (e.g. esophageal stricture or achalasia), AND have at least two of the following:

- . Age greater than 75 years old
- . A prior fragility fracture
- . A bone mineral density (BMD) T-score less than or equal to -2.5

NOTE: Patients receiving Aclasta should not be receiving concomitant bisphosphonate therapy. The recommended dose of Aclasta (zoledronic acid) is a single IV injection of 5mg, once yearly.

LU Authorization Period: Indefinite.

## New Off-Formulary Interchangeable (OFI) Products

| DIN/PIN                                               | BRAND NAME               | STRENGTH | DOSAGE FORM | MFR | UNIT COST |
|-------------------------------------------------------|--------------------------|----------|-------------|-----|-----------|
| 02425947                                              | Mint-Hydrochlorothiazide | 12.5mg   | Tab         | MIN | 0.0322    |
| <i>(Interchangeable with PMS-Hydrochlorothiazide)</i> |                          |          |             |     |           |

| DIN/PIN                                     | BRAND NAME         | STRENGTH | DOSAGE FORM        | MFR | UNIT COST |
|---------------------------------------------|--------------------|----------|--------------------|-----|-----------|
| 02423944                                    | PMS-Olanzapine ODT | 20mg     | Rapid Dissolve Tab | PMS | 7.5977    |
| <i>(Interchangeable with Zyprexa Zydis)</i> |                    |          |                    |     |           |

| DIN/PIN                             | BRAND NAME    | STRENGTH | DOSAGE FORM | MFR | UNIT COST |
|-------------------------------------|---------------|----------|-------------|-----|-----------|
| 02421364                            | Ran-Memantine | 10mg     | Tab         | RAN | 1.6357    |
| <i>(Interchangeable with Ebixa)</i> |               |          |             |     |           |

| DIN/PIN                               | BRAND NAME     | STRENGTH | DOSAGE FORM | MFR | UNIT COST |
|---------------------------------------|----------------|----------|-------------|-----|-----------|
| 02420260                              | Teva-Modafinil | 100mg    | Tab         | TEV | 0.9293    |
| <i>(Interchangeable with Alertec)</i> |                |          |             |     |           |

| DIN/PIN                                          | BRAND NAME                                | STRENGTH | DOSAGE FORM    | MFR | UNIT COST |
|--------------------------------------------------|-------------------------------------------|----------|----------------|-----|-----------|
| 02422425                                         | Zoledronic Acid for Injection Concentrate | 4mg/5mL  | Inj Sol-5mL Pk | DRR | 415.5600  |
| <i>(Interchangeable with Zometa Concentrate)</i> |                                           |          |                |     |           |



# New Nutrition Product

| DIN/PIN  | PRODUCT NAME              | STRENGTH   | DOSAGE FORM        | MFR | COST/PKG | AMOUNT MOH PAYS | AMOUNT PATIENT PAYS |
|----------|---------------------------|------------|--------------------|-----|----------|-----------------|---------------------|
| 09857497 | KetoCal 4:1 (Unflavoured) | 1.5kcal/mL | Liq-237mL Tetra Pk | NUT | 5.7463   | 5.7463          | 0.0000              |

# Change to Reason For Use Content

| DIN/PIN  | BRAND NAME | STRENGTH | DOSAGE FORM | MFR |
|----------|------------|----------|-------------|-----|
| 02378604 | Xarelto    | 15mg     | Tab         | BAH |
| 02378612 | Xarelto    | 20mg     | Tab         | BAH |

## ***Updated Reason For Use Code 444***

For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) for up to six (6) months.

LU Authorization Period: 6 months.

### Notes:

- The recommended dose of rivaroxaban for patients initiating DVT treatment is 15mg twice daily for 3 weeks, followed by 20mg once daily.
- ODB Program coverage for rivaroxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, rivaroxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.
- Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph).

# Addition of New Reason For Use Code

| DIN/PIN  | BRAND NAME            | STRENGTH | DOSAGE FORM | MFR |
|----------|-----------------------|----------|-------------|-----|
| 02308894 | Granisetron           | 1mg      | Tab         | AAP |
| 02291967 | Ondansetron           | 4mg/5mL  | O/L         | AAP |
| 02229639 | Zofran                | 4mg/5mL  | O/L         | GSK |
| 02288184 | Apo-Ondansetron       | 4mg      | Tab         | APX |
| 02296349 | Co Ondansetron        | 4mg      | Tab         | COB |
| 02313685 | Jamp-Ondansetron      | 4mg      | Tab         | JPC |
| 02371731 | Mar-Ondansetron       | 4mg      | Tab         | MAR |
| 02305259 | Mint-Ondansetron      | 4mg      | Tab         | MIN |
| 02297868 | Mylan-Ondansetron     | 4mg      | Tab         | MYL |
| 02306212 | Ondansetron-Odan      | 4mg      | Tab         | ODN |
| 02258188 | PMS-Ondansetron       | 4mg      | Tab         | PMS |
| 02278618 | Phl-Ondansetron       | 4mg      | Tab         | PHE |
| 02312247 | Ran-Ondansetron       | 4mg      | Tab         | RAN |
| 02278529 | Ratio-Ondansetron     | 4mg      | Tab         | RPH |
| 02274310 | Sandoz Ondansetron    | 4mg      | Tab         | SDZ |
| 02376091 | Septa-Ondansetron     | 4mg      | Tab         | SET |
| 02264056 | Teva-Ondansetron      | 4mg      | Tab         | TEV |
| 02213567 | Zofran                | 4mg      | Tab         | GSK |
| 02344440 | Zym-Ondansetron       | 4mg      | Tab         | ZYN |
| 02389983 | Ondissolve ODF (Film) | 4mg      | Film        | TAK |
| 02239372 | Zofran ODT (Tablet)   | 4mg      | Tab         | GSK |

## **New Reason For Use Code and Clinical Criteria in addition to the existing codes**

### **Code 454**

For the treatment of emesis in cancer patients receiving moderately emetogenic chemotherapy (MEC) regimens.

LU Authorization Period: 1 year.

### Addition of New Reason For Use Code (Cont'd...)

| DIN/PIN  | BRAND NAME            | STRENGTH | DOSAGE<br>FORM | MFR |
|----------|-----------------------|----------|----------------|-----|
| 02288192 | Apo-Ondansetron       | 8mg      | Tab            | APX |
| 02296357 | Co Ondansetron        | 8mg      | Tab            | COB |
| 02313693 | Jamp-Ondansetron      | 8mg      | Tab            | JPC |
| 02371758 | Mar-Ondansetron       | 8mg      | Tab            | MAR |
| 02305267 | Mint-Ondansetron      | 8mg      | Tab            | MIN |
| 02297876 | Mylan-Ondansetron     | 8mg      | Tab            | MYL |
| 02306220 | Ondansetron-Odan      | 8mg      | Tab            | ODN |
| 02258196 | PMS-Ondansetron       | 8mg      | Tab            | PMS |
| 02278626 | Phl-Ondansetron       | 8mg      | Tab            | PHE |
| 02312255 | Ran-Ondansetron       | 8mg      | Tab            | RAN |
| 02278537 | Ratio-Ondansetron     | 8mg      | Tab            | RPH |
| 02274329 | Sandoz Ondansetron    | 8mg      | Tab            | SDZ |
| 02376105 | Septa-Ondansetron     | 8mg      | Tab            | SET |
| 02264064 | Teva-Ondansetron      | 8mg      | Tab            | TEV |
| 02213575 | Zofran                | 8mg      | Tab            | GSK |
| 02344459 | Zym-Ondansetron       | 8mg      | Tab            | ZYN |
| 02389991 | Ondissolve ODF (Film) | 8mg      | Film           | TAK |
| 02239373 | Zofran ODT (Tablet)   | 8mg      | Tab            | GSK |

### New Reason For Use Code and Clinical Criteria in addition to the existing codes

#### **Code 454**

For the treatment of emesis in cancer patients receiving moderately emetogenic chemotherapy (MEC) regimens.

LU Authorization Period: 1 year.

# Drug Benefit Price (DBP) Changes

| DIN/PIN  | BRAND NAME            | STRENGTH      | DOSAGE FORM       | MFR | DBP     |
|----------|-----------------------|---------------|-------------------|-----|---------|
| 09853758 | Haloperidol LA        | 100mg/mL Oily | Inj Sol-5mL Pk    | SDZ | 84.6150 |
| 02403420 | Humalog Mix25 Kwikpen | 25% & 75%     | Inj Susp-5x3mL Pk | LIL | 55.9200 |

# OFI Product Price Change

| DIN/PIN  | BRAND NAME   | STRENGTH | DOSAGE FORM | MFR | UNIT COST |
|----------|--------------|----------|-------------|-----|-----------|
| 02420333 | Apo-Adefovir | 10mg     | Tab         | APX | 20.4400   |

# Nutrition Product Name Change

| DIN/PIN  | CURRENT<br>PRODUCT NAME | NEW PRODUCT<br>NAME                | STRENGTH   | DOSAGE FORM        | MFR |
|----------|-------------------------|------------------------------------|------------|--------------------|-----|
| 09857388 | KetoCal 4:1             | KetoCal 4:1<br>(Vanilla Flavoured) | 1.5kcal/mL | Liq-237mL Tetra Pk | NUT |

# Discontinued Products

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

| DIN/PIN  | BRAND NAME         | STRENGTH           | DOSAGE FORM      | MFR |
|----------|--------------------|--------------------|------------------|-----|
| 02017598 | Drisdol            | 8288IU/mL          | O/L              | SAV |
| 02243789 | Ratio-IPRA SAL UDV | 500mcg/2.5mg/2.5mL | Inh Sol-2.5mL Pk | RPH |
| 01926624 | Tamofen            | 10mg               | Tab              | SAV |
| 01926632 | Tamofen            | 20mg               | Tab              | SAV |
| 02221977 | Trental            | 400mg              | SR Tab           | SAV |



# Delisted Products

| DIN/PIN   | BRAND NAME       | STRENGTH    | DOSAGE FORM    | MFR |
|-----------|------------------|-------------|----------------|-----|
| 00386715  | Cytosar          | 100mg       | Inj Pd-Vial Pk | PFI |
| 00396818  | Apo-Haloperidol  | 1mg         | Tab            | APX |
| 00463698  | Apo-Haloperidol  | 10mg        | Tab            | APX |
| 00176095  | Cafergot         | 1mg & 100mg | Tab            | NOV |
| 01907107* | Monopril         | 10mg        | Tab            | BQU |
| 01907115* | Monopril         | 20mg        | Tab            | BQU |
| 02162431  | Naprosyn         | 25mg/mL     | O/L            | HLR |
| 02378884  | Simvastatin-Odan | 5mg         | Tab            | ODN |
| 02378892  | Simvastatin-Odan | 10mg        | Tab            | ODN |
| 02378906  | Simvastatin-Odan | 20mg        | Tab            | ODN |
| 02378914  | Simvastatin-Odan | 40mg        | Tab            | ODN |
| 02378922  | Simvastatin-Odan | 80mg        | Tab            | ODN |

\* Remain in the Formulary as reference product.

