BULLETIN # 116

Manitoba Drug Benefits and Manitoba Drug Interchangeability Formulary Amendments

The following amendments will take effect on February 24, 2022

The amended Manitoba Drug Benefits Formulary and Manitoba Drug Interchangeability Formulary will be available on the Manitoba Health website http://www.gov.mb.ca/health/mdbif on the effective date of February 24, 2022

Bulletin 116 is currently available for download:
http://www.gov.mb.ca/health/mdbif/bulletin116.pdf

Please also refer to the psv/excel files* found on the Manitoba Health website under "Notices" here:

https://www.gov.mb.ca/health/pharmacare/healthprofessionals.html

***The psv/excel files contain the following information: DIN, PRODUCT NAME, UNIT PRICE (List Price + 5%) & LOWEST GENERIC PRICE (List Price + 5%)**

Inside This Issue

Part 1 Additions

DIN	TRADE NAME	GENERIC	STRENGTH	FORM	MFR*
02498685 02498707 02498693	**Atectura Breezhaler**	indacaterol/mometasone furoate	150/80 mcg 150/160 mcg 150/320 mcg	Capsule	NVT
02475022 02475030 02475049 02475057	**Atorvastatin**	atorvastatin	10 mg 20 mg 40 mg 80 mg	Tablet	LRI
02514982 02514990	**Capecitabine**	capecitabine	150 mg 500 mg	Tablet	SAH
02475278 02475286	**Donepezil**	donepezil	5 mg 10 mg	Tablet	LRI
02499967	**Duobrii**	halobetasol propionate/ tazarotene	0.01/0.045 %	Topical Lotion	BHC
00727369	**Estragyn**	estrone	0.1 %	Vaginal Cream	SLP
02504197 02504200 02504219 02504235	**Jamp Atorvastatin Calcium**	atorvastatin	10 mg 20 mg 40 mg 80 mg	Tablet	JPC
02509911	**Jamp Buspirone**	buspirone	10 mg	Tablet	JPC
02442817 02442825	**Jamp Trazodone**	trazodone	100 mg 150 mg	Tablet	JPC
02508028	**Mint-Capecitabine**	capecitabine	500 mg	Tablet	MPH
02499509	**Nexplanon**	etonogestrel	68 mg	Implant	ORG
02503794 02503808	**NRA-Telmisartan**	telmisartan	40 mg 80 mg	Tablet	NRA
02517116	**pmsc-Celecoxib**	celecoxib	100 mg	Capsule	PMS
02270889	**Riva-Alendronate**	alendronate	70 mg	Tablet	LRI
02392259	**Riva-Anastrozole**	anastrozole	1 mg	Tablet	LRI
02398656	**Riva-Letrozole**	letrozole	2.5 mg	Tablet	LRI
02515520 02515539	**Ursodiol C**	ursodiol	250 mg 500 mg	Tablet	SAH

Part 2 Additions

02304376	**pms-Desmopressin**	desmopressin	0.2 mg	Tablet	PMS

For the treatment of:
(a) diabetes insipidus; and
(b) enuresis in children refractory to alternate agents.

02275309	**Riva-Azithromycin**	azithromycin	250 mg	Tablet	LRI

For the treatment of patients:
(a) not responding to or intolerant of alternative antibiotics (e.g.amoxicillin and erythromcyin);
(b) with mycobacterial infections due to mycobacterium avium and mycobacterium intracellulare;
(c) with sexually transmitted disease due to Chlamydia;
(d) with pneumonia;
(e) with infections requiring a macrolide (including CAP in patients 65 and older) with documented intolerance to erythromycin.

02455013	**Riva-Finasteride**	finasteride	5 mg	Tablet	LRI

For the treatment of symptomatic benign prostatic hyperplasia.

Exception Drug Status Additions

02495341 02495368	**ACH-Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Delayed Release Capsule	ACH
02505762 02505770	**Apo-Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Delayed Release Capsule	APX
02494809 02494817	**GLN-Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Delayed Release Capsule	GLM
02516047 02516055	**Jamp Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Delayed Release Capsule	JPC
02502690 02502704	**Mar-Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Delayed Release Capsule	MAR
02497026 02497034	**pms-Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Delayed Release Capsule	PMS
02513781 02513803	**Sandoz Dimethyl Fumarate**	dimethyl fumarate	120 mg 240 mg	Delayed Release Capsule	SDZ

For the treatment of patients 18 years or older who have relapsing-remitting multiple sclerosis (RRMS) when prescribed by a neurologist from the Manitoba MS Clinic.

02424770 02483327	**Actemra SC** *(new indication)*	tocilizumab	162 mg/0.9 mL 162 mg/0.9 mL	Injection	HLR

As per Actemra criteria for Systemic Juvenile Idiopathic Arthritis (sJIA) and Polyarticular Juvenile Idiopathic Arthritis (pJIA)
https://www.gov.mb.ca/health/mdbif/docs/edsnotice.pdf

02497220 02497247	**Cabenuva**	cabotegravir/rilpivirine	200/300 mg/mL	KIT - Injection	VII

As a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically stable and suppressed (HIV-1 RNA less than 50 copies /mL) and have tolerated a trial of oral cabotegravir and rilpivirine.

02491788	**Calquence**	acalabrutinib	100 mg	Capsule	AZC

Relapsed or refractory CLL

- As monotherapy in adult patients with relapsed or refractory Chronic Lymphocytic Leukemia (CLL) who have received at least one prior therapy.
- Eligible patients must have active disease according to one or more of the International Workshop on Chronic Lymphocytic Leukemia (iwCLL) 2008 criteria, and good performance status.
- Treatment with acalabrutinib should be continued until disease progression or unacceptable toxicity.

Previously untreated CLL

- As monotherapy in adult patients with previously untreated CLL for whom a fludarabine-based regimen is inappropriate.
- Eligible patients include those who are 65 years of age or older, or between 18 and 65 years of age with comorbidities (defined as creatinine clearance between 30 to 69 mL/min or a Cumulative Illness Rating Scale [CIRS] for geriatrics score > 6), who have active disease according to one or more of the International Workshop on Chronic Lymphocytic Leukemia (iwCLL) 2008 criteria and good performance status.
- Treatment with acalabrutinib should be continued until disease progression or unacceptable toxicity.

02483629 02483637 02483645	**Crysvita**	burosumab	10 mg/mL 20 mg/mL 30 mg/mL	Injection	UGX

For the treatment of X-linked hypophosphatemia (XLH) only if the following conditions are met:

Initiation Criteria

- Treatment can be initiated in pediatric patients who are at least one year of age and in whom epiphyseal closure has not yet occurred, who have:
  - a clinical presentation consistent with XLH, including:
    - fasting hypophosphatemia, and
    - normal renal function (defined as fasting serum creatinine below the age-adjusted upper limit of normal), and
  - radiographic evidence of rickets with a rickets severity score (RSS) total score of two or greater, and
  - a confirmed phosphate-regulating endopeptidase homolog, X-linked (PHEX) gene variant in either the patient or in a directly related family member with appropriate X-linked inheritance.

Renewal Criteria

Patients should be assessed on an annual basis. Treatment with burosumab can be renewed as long as the patient does not meet any of the following discontinuation criteria.

Discontinuation Criteria

- In pediatric patients in whom epiphyseal closure has not yet occurred, reimbursement of treatment with burosumab should be discontinued if:
  - the 12-month RSS total score has not improved from baseline, when baseline represents the initiation of treatment, or
  - the RSS total score achieved after the first 12 months of therapy has not been maintained subsequently.
- In adolescent or adult patients who initiated burosumab based on the aforementioned criteria for pediatric patients, burosumab should be discontinued if any of the following occur: hyperparathyroidism, nephrocalcinosis, or evidence of fracture or pseudofracture based on radiographic assessment.

Prescribing Conditions

Burosumab should only be prescribed by a physician working in a comprehensive team of health care providers who are experienced in the diagnosis and management of XLH.

02501244	**Enerzair Breezhaler**	glycopyrronium/indacaterol/ mometasone furoate	50/150/160 mcg	Capsule	NVT

For the treatment of asthma in adult patients inadequately controlled with a maintenance combination of a long-acting beta-2 agonist (LABA) and a medium or high dose of an inhaled corticosteroid (ICS), who have experienced one or more asthma exacerbations in the previous 12 months.

02435462 02435470	**Forxiga** *(new indication)*	dapagliflozin	5 mg 10 mg	Tablet	AZC

For adult patients with New York Heart Association (NYHA) class II and III heart failure, as an adjunct to standard of care therapy, for the treatment of heart failure with reduced ejection fraction (HFrEF) [Left ventricular ejection fraction (LVEF) $\leq$ 40%]. Standard of care therapies include beta-blockers angiotensin converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs), plus a mineralocorticoid receptor antagonist.

02516098	**Ilumya**	tildrakizumab	100 mg/mL	Injection	SPG

For treatment of adult patients with severe plaque psoriasis presently with one or more of the following:

- Psoriasis Area and the Severity Index (PASI) ≥ 10
- Body Surface Area (BSA) > 10%
- Significant involvement of the face, hands, feet or genital region
- Dermatology Life Quality Index (DLQI) > 10 AND
- Failure to respond to, contraindications to, intolerant of or unable to access methotrexate, cyclosporine and/or phototherapy.

Coverage will be approved initially for a maximum of 4 months. For continued coverage the physician must confirm the patient's response to treatment and demonstration of treatment clinical benefits:

- ≥ 50% reduction in the PASI score with ≥ 5 point improvement in the DLQI
- ≥ 75 % reduction in the PASI score
- ≥ 50% reduction in the BSA with significant improvement of the face, hands, feet or genital region.

Request for coverage must be made by a specialist in dermatology.

02514702 02514710	**Jamp Pirfenidone**	pirfenidone	267 mg 801 mg	Tablet	JPC

For the treatment of adult patients who have a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF) confirmed by a respirologist.
Complete criteria may be obtained from the EDS office at Manitoba Health.

02496429 02496437	**Mayzent**	siponimod	0.25 mg 2 mg	Tablet	NVT

For the treatment of patients with active secondary progressive multiple sclerosis (SPMS), when prescribed by a neurologist from the Manitoba Multiple Sclerosis (MS) Clinic.

02513447	**Riabni**	rituximab	10 mg/mL	Injection	AGA

For the treatment of severely active rheumatoid arthritis (RA), in combination with methotrexate, for patients who have failed to respond to an adequate trial of one or more anti-tumor necrosis factor (anti-TNF) agents (monoclonal antibody OR fusion protein) OR who are contraindicated to anti-TNF agents.

Request for coverage must be made by a specialist in rheumatology.

As induction-remission therapy for patients with severely active Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA) in whom:

- the use of cyclophosphamide has failed; or
- the use of cyclophosphamide is not appropriate

Riabni will be a preferred rituximab option for all rituximab-naïve patients prescribed a rituximab product for rheumatoid arthritis, Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA). Preferred means the first rituximab product to be considered for reimbursement for rituximab-naive patients. Patients will not be permitted to switch from Riabni to another rituximab product or vice versa, if:

- Previously trialed and deemed unresponsive to therapy.

02458039 02458047 02458055	**Venclexta** *(new indication)*	venetoclax	10 mg 50 mg 100 mg	Tablet	ABV
02458063	**Venclexta Starter** *(new indication)*	venetoclax	10/100/50 mg	KIT - Tablet	ABV

Venetoclax with Obinutuzumab:

- Venetoclax in combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL) who are fludarabine ineligible.
- Patients should have previously untreated CLL, be fludarabine ineligible as indicated by either a Cumulative Illness Rating Scale (CIRS) score greater than 6 or a creatinine clearance (CrCl) less than 70 mL per minute, require treatment according to the International Workshop on Chronic Lymphoma Leukemia criteria, and have good performance status.
- Treatment should be given for a total of 12 months as a finite treatment: for six 28-day cycles in combination with obinutuzumab followed by six months of venetoclax as a single agent.

02458039 02458047 02458055	**Venclexta** *(new indication)*	venetoclax	10 mg 50 mg 100 mg	Tablet	ABV

Venetoclax with Azacitidine:
Venetoclax in combination with azacitidine should be reimbursed for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy if the following conditions are met:

- Patients with AML who are considered ineligible for standard intensive induction chemotherapy are defined as either of the following:
  - Age 75 years or older and an ECOG performance status of 0 to 2
  - Age 18 to 74 years and fulfill at least one of the following:
    - ECOG performance status of 2 to 3
    - History of congestive heart failure requiring treatment, ejection fraction ≤50%, or chronic stable angina
    - DLCO ≤65% or FEV1 ≤65%
    - Creatinine clearance ≥30 mL/min to 45 mL/min
    - Moderate hepatic impairment with total bilirubin >1.5 to ≤3.0 ULN
- Venetoclax plus azacitidine should be initiated in patients with no prior history of receiving a hypomethylating agent, venetoclax, or chemotherapy for MDS (Myelodysplastic Syndromes)
- Venetoclax plus azacitidine should be reimbursed in patients who continue to receive clinical benefit from the treatment and do not have intolerable toxicity.
- For patients without unacceptable toxicity, it is recommended that patients be treated for a minimum of 6 cycles.
- Treatment with the venetoclax plus azacitidine should be discontinued upon the occurrence of any of the following:
  - Progressive disease (per ELN (European LeukemiaNet) criteria)
  - Intolerable toxicity
- If a patient stops treatment with the azacitidine component for reasons other than disease progression (e.g., toxicity or intolerance), venetoclax should also be discontinued.
- Venetoclax plus azacitidine should only be prescribed by clinicians who:
  - have expertise in diagnosis and management of patients with AML
  - are familiar with the toxicity profile associated with the venetoclax and azacitidine regimen.

02497204	**Vocabria**	cabotegravir	30 mg	Tablet	VII

For the treatment of human immunodeficiency virus type 1 (HIV-1) infection in combination with rilpivirine tablets in adults who are virologically stable and suppressed (HIV-1 RNA less than 50 copies /mL):

- Prior to initiation of injectable cabotegravir and rilpivirine; or
- To accommodate oral bridging therapy for patients previously established on injectable cabotegravir and rilpivirine who have experienced treatment interruption.

New Interchangeable Categories

Dimethyl Fumarate - 120 mg - Delayed Release Capsules			$	$ + 5%
02404508	Tecfidera	BIG	18.3871	19.3065
02495341	ACH-Dimethyl Fumarate	ACH	4.4266	4.6479
02505762	Apo-Dimethyl Fumarate	APX	4.4266	4.6479
02494809	GLN-Dimethyl Fumarate	GLM	4.4266	4.6479
02516047	Jamp Dimethyl Fumarate	JPC	4.4266	4.6479
02502690	Mar-Dimethyl Fumarate	MAR	4.4266	4.6479
02497026	pms-Dimethyl Fumarate	PMS	4.4266	4.6479
02513781	Sandoz Dimethyl Fumarate	SDZ	4.4266	4.6479

Dimethyl Fumarate - 240 mg - Delayed Release Capsules			$	$ + 5%
02420201	Tecfidera	BIG	36.7734	38.6121
02495368	ACH-Dimethyl Fumarate	ACH	8.6888	9.1232
02505770	Apo-Dimethyl Fumarate	APX	8.6888	9.1232
02494817	GLN-Dimethyl Fumarate	GLM	8.6888	9.1232
02516055	Jamp Dimethyl Fumarate	JPC	8.6888	9.1232
02502704	Mar-Dimethyl Fumarate	MAR	8.6888	9.1232
02497034	pms-Dimethyl Fumarate	PMS	8.6888	9.1232
02513803	Sandoz Dimethyl Fumarate	SDZ	8.6888	9.1232

New Interchangeable Products

The following products have been added to existing interchangeable drug categories:

Alendronate - 70 mg - Tablets			$	$ + 5%
02270889	Riva-Alendronate	LRI	2.1014	2.2065

Anastrozole - 1 mg - Tablets			$	$ + 5%
02392259	Riva-Anastrozole	LRI	0.9522	1.0000

Atorvastatin - 10 mg - Tablets			$	$ + 5%
02475022	Atorvastatin	LRI	0.1743	0.1831
02504197	Jamp Atorvastatin Calcium	JPC	0.1743	0.1831

Atorvastatin - 20 mg - Tablets			$	$ + 5%
02475030	Atorvastatin	LRI	0.2179	0.2288
02504200	Jamp Atorvastatin Calcium	JPC	0.2179	0.2288

Atorvastatin - 40 mg - Tablets			$	$ + 5%
02475049	Atorvastatin	LRI	0.2342	0.2459
02504219	Jamp Atorvastatin Calcium	JPC	0.2342	0.2459

Atorvastatin - 80 mg Tablets			$	$ + 5%
02475057	Atorvastatin	LRI	0.2342	0.2459
02504235	Jamp Atorvastatin Calcium	JPC	0.2342	0.2459

Azithromycin - 250 mg - Tablets			$	$ + 5%
02275309	Riva-Azithromycin	LRI	0.9410	0.9881

Buspirone - 10 mg - Tablets			$	$ + 5%
02509911	Jamp Buspirone	JPC	0.2713	0.2849

Capecitabine - 150 mg - Tablets			$	$ + 5%
02514982	Capecitabine	SAH	0.4575	0.4804

Capecitabine - 500 mg - Tablets			$	$ + 5%
02514990	Capecitabine	SAH	1.5250	1.6013
02508028	Mint-Capecitabine	MPH	1.5250	1.6013

Celecoxib - 100 mg - Capsules				**$**	**$ + 5%**
	02517116	pmsc-Celecoxib	PMS	0.1279	0.1343

Desmopressin - 0.2 mg - Tablets				**$**	**$ + 5%**
	02304376	pms-Desmopressin	PMS	1.3217	1.3878

Donepezil - 5 mg - Tablets				**$**	**$ + 5%**
	02475278	Donepezil	LRI	0.4586	0.4815

Donepezil - 10 mg - Tablets				**$**	**$ + 5%**
	02475286	Donepezil	LRI	0.4586	0.4815

Finasteride - 5 mg - Tablets				**$**	**$ + 5%**
	02455013	Riva-Finasteride	LRI	0.4138	0.4345

Letrozole - 2.5 mg - Tablets				**$**	**$ + 5%**
	02398656	Riva-Letrozole	LRI	1.3780	1.4469

Pirfenidone - 267 mg - Tablets				**$**	**$ + 5%**
	02514702	Jamp Pirfenidone	JPC	6.7120	7.0476

Pirfenidone - 801 mg - Tablets				**$**	**$ + 5%**
	02514710	Jamp Pirfenidone	JPC	20.1360	21.1428

Telmisartan - 40 mg - Tablets				**$**	**$ + 5%**
	02503794	NRA-Telmisartan	NRA	0.2161	0.2269

Telmisartan - 80 mg - Tablets				**$**	**$ + 5%**
	02503808	NRA-Telmisartan	NRA	0.2161	0.2269

Tolterodine - 2 mg - Tablets				**$**	**$ + 5%**
	02299607	Teva-Tolterodine	TEV	0.2455	0.2578

Trazodone HCl - 100 mg - Tablets				**$**	**$ + 5%**
	02442817	Jamp Trazodone	JPC	0.1570	** 0.1649

Trazodone HCl - 150 mg Tablets				**$**	**$ + 5%**
	02442825	Jamp Trazodone	JPC	0.1453	0.1526

Ursodiol - 250 mg - Tablets				**$**	**$ + 5%**
	02515520	Ursodiol C	SAH	0.3818	0.4009

Ursodiol - 500 mg - Tablets				**$**	**$ + 5%**
	02515539	Ursodiol C	SAH	0.7242	0.7604

** The price has resulted in a change to the lowest price in the category.

Interchangeable Product Price Changes

The following changes in prices have occurred: **($)** **($ + 5%)**

02147645	Apo-Trazodone	trazodone	100 mg	Tablet	0.1570	** 0.1649
01937235	pms-Trazodone	trazodone	100 mg	Tablet	0.1570	** 0.1649
02144271	Teva-Trazodone	trazodone	100 mg	Tablet	0.1570	** 0.1649
02348780	Trazodone	trazodone	100 mg	Tablet	0.1570	** 0.1649

** The price has resulted in a change to the lowest price in the category.

Product Deletions

(as identified for deletion in Bulletin # 115)

The following products have been deleted.

02179709	Lozide	indapamide	1.25 mg	Tablet
02349191	Alprazolam	alprazolam	0.25 mg	Tablet
02351080	Lorazepam	lorazepam	1 mg	Tablet
01930672	Penicillin G Sodium	penicillin g sodium	1,000,000 u	Powder for Solution
02443368	Tobramycin	tobramycin	60 mg/mL	Inhalation Solution

Discontinued Products

The following products will be deleted with the next Formulary amendments and will appear as "Product Deletions" on Bulletin # 118.

00582301	Dalacin T	clindamycin	1 %	Topical Solution
02190915	Losec	omeprazole	20 mg	Tablet
00010383 00010391	Sintrom	acenocoumarol	1 mg 4 mg	Tablet
02248761	Viracept	nelfinavir	625 mg	Tablet
02349205	Alprazolam	alprazolam	0.5 mg	Tablet
02391562 02391570	Bupropion SR	bupropion	100 mg 150 mg	Tablet
02389096 02389118	Mar-Olanzapine ODT	olanzapine	10 mg 15 mg	Orally Disintegrating Tablets
02392992 02393018 02393026	Mint-Irbesartan/HCTZ	irbesartan/HCTZ	150 mg/12.5 mg 300 mg/12.5 mg 300 mg/25 mg	Tablet
02413485 02413493 02413507 02413515 02413523	Mylan-Risperidone ODT	risperidone	0.5mg 1 mg 2 mg 3 mg 4 mg	Orally Disintegrating Tablets
00792659	pms-Chloral Hydrate	chloral hydrate	100 mg/5 mL	Syrup
00839264	pms-Ibuprofen	ibuprofen	600 mg	Tablet
02148773 02015951	pms-Ketoprofen	ketoprofen	50 mg 100 mg	Suppository
00584339	pms-Metronidazole	metronidazole	250 mg	Tablet
02481979	Sandoz Methadone	methadone	10 mg/mL	Solution