BULLETIN # 129

Manitoba Drug Benefits Formulary and Manitoba Drug Interchangeability Formulary Amendments

The following amendments will take effect on December 21, 2023

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 December 21, 2023

Bulletin #129 is currently available for download:
http://www.gov.mb.ca/health/mdbif/bulletin129.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%)**

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Part 1 Additions

DIN	TRADE NAME	GENERIC	STRENGTH	FORM	MFR*
02478587	**Amlodipine**	amlodipine	2.5mg	Tablet	SAH
02529904	**Anastrozole**	anastrozole	1mg	Tablet	SIP
02529696 02529718	**M-Solifenacin Succinate**	solifenacin succinate	5mg 10mg	Tablet	MNP
02408880 02408899 02408902	**Mint-Gabapentin**	gabapentin	100mg 300mg 400mg	Capsule	MPH
02538601	**Odan-Amantadine Syrup**	amantadine hydrochloride	10mg/ml	Syrup	ODN
02537990 02538008 02537982	**pms-Perindopril-Indapamide**	perindopril erbumine/ indapamide	2mg/0.625mg 4mg/1.25mg 8mg/2.5mg	Tablet	PMS
02467860	**Tresiba** *(new format)*	insulin degludec	100unit/ml	Solution	NOO

* Abbreviation of manufacturers' name

Part 2 Additions

02530015	**Auro-Tofacitinib**	tofacitinib	10mg	Tablet	AUP
02511312	**Taro-Tofacitinib**	tofacitinib	10mg	Tablet	TAR

For the treatment of patients 18 years of age or older with moderate to severe active ulcerative colitis who have had inadequate response, intolerance or contraindications to conventional therapy including 5-aminosalicylate compounds AND corticosteroids.

NOTE: Coverage will be provided only if prescribed by a specialist in gastroenterology.

PIN	Product	MFR	Approved Quantity
00905508	**Dexcom G7 Sensor**	DCC	45 per benefit year
00905513	**Dexcom G7 Receiver**	DCC	1 per client lifetime

For patients with type 1 or type 2 diabetes currently on both basal and bolus insulin or using an insulin pump.

02533316 02533324	**Sandoz Alfacalcidol**	alfacalcidol	0.25mcg 1mcg	Capsule	SDZ

For the management of hypocalcemia and osteodystrophy in patients with chronic renal failure undergoing dialysis and in the managment of hypocalcemia in clinical manifestations associated with post surgical hypoparathyroidism, idiopathic hypoparathyroidism, pseudohypoparathyroidism, and Vitamin D resistant rickets.

02423898	**Xeljanz** *(updated criteria)*	tofacitinib	5 mg	Tablet	PFI
02530007	**Auro-Tofacitinib** *(updated criteria)*	tofacitinib	5 mg	Tablet	AUP
02522799	**pms-Tofacitinib** *(updated criteria)*	tofacitinib	5 mg	Tablet	PMS
02511304	**Taro-Tofacitinib** *(updated criteria)*	tofacitinib	5 mg	Tablet	TAR

For the treatment of patients 18 years of age or older who have moderate to severe active rheumatoid arthritis and have:
(a) failed treatment with at least 3 DMARD therapies, one of which is methotrexate or leflunomide or both, unless intolerance or contraindications to these agents is documented;
(b) tried one combination therapy of DMARDS; and
(c) documented disease activity (such as the number of tender joints, the number of swollen joints, the erythrocyte sedimentation rate or C-reactive protein value).

NOTE: Coverage will be provided only if prescribed by a specialist in rheumatology.

Combined use with other biologic drugs or Janus kinase (JAK) inhibitors will not be reimbursed.

Exceptional Drug Status Additions

02480824 02480832 02480840	**Cabometyx** *(new indication)*	cabozantinib	20 mg 40 mg 60 mg	Tablet	IPL

Differentiated Thyroid Carcinoma (DTC)

For the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC).

Eligible patients should meet all of the following criteria:

- Refractory to prior radioactive iodine therapy (RAI-R) or not eligible for RAI.
- Previously treated with 1 to 2 prior vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR)-targeting TKIs.
- Have good performance status.

02528363 02528371 02528398	**Cibinqo**	abrocitinib	50 mg 100 mg 200 mg	Tablet	PFI

For the treatment of refractory moderate to severe[1] atopic dermatitis (AD), in patients aged 12 years and older, only if the following criteria are met:

Initiation Criteria

• Patient has had an adequate trial [2] (with a documented refractory disease), or was intolerant (with documented intolerance), or is ineligible for each of the following therapies:

- maximally tolerated medical topical therapies for AD combined with phototherapy (where available); AND

- maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine).

• The physician must provide the Eczema Area and Severity Index (EASI) score at the time of initial request for reimbursement.

Initial approval: 6 months

Renewal Criteria

• The physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) 6 months after treatment initiation.

• The physician must provide proof of maintenance of EASI-75 response from baseline for subsequent authorizations.

Renewal approval: 1 year

Request for coverage must be made by, or in consultation with, a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD.

Abrocitinib should not be used in combination with phototherapy, any immunomodulatory agents (including biologics) or other Janus kinase [JAK] inhibitor treatment for moderate to severe AD.

[1] Moderate to severe atopic dermatitis is defined as an EASI score of 16 points or higher.

[2] Adequate trials are defined as:

- Phototherapy – 3 times a week for 12 weeks.
- Methotrexate – 10 to 20mg per week for 12 weeks.
- Cyclosporine – 2.5 to 5mg/kg/day for 12 weeks.
- Mycophenolate mofetil – 1g twice daily for 12 weeks.
- Azathioprine – 1.5 to 2.5mg/kg/day for 12 weeks.

02525569	**Cosentyx** *(new strength)*	secukinumab	75 MG/0.5 ML	Injection	NVT

See Bulletin #89 and #98 for criteria:
https://www.gov.mb.ca/health/mdbif/docs/bulletins/bulletin89.pdf
https://www.gov.mb.ca/health/mdbif/docs/bulletins/bulletin98.pdf

02533472	**Hadlima** *(new strength)*	adalimumab	40 mg/0.4 ml	Pre-filled Syringe	SBC
02533480	**Hadlima** *(new strength)*	adalimumab	40 mg/0.4 ml	Auto-Injector	SBC

See Bulletin #112 for criteria:
https://www.gov.mb.ca/health/mdbif/docs/bulletins/bulletin112.pdf

02484056 02468220 02450321 02484129 02450313 02450305 02450291	**Lenvima** *(new indications)*	lenvatinib	4 mg 8 mg 10 mg 12 mg 14 mg 20 mg 24 mg	Capsule	EIS

• Lenvatinib combined with pembrolizumab for the treatment of adult patients with advanced endometrial carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior platinum-based systemic therapy, and are not candidates for curative surgery or radiation.

• Lenvatinib combined with pembrolizumab for the treatment of adult patients with advanced (not amenable to curative surgery or radiation) or metastatic renal cell carcinoma (RCC) who have had no prior systemic therapy for metastatic disease.

02485966 02485974	**Lorbrena**	lorlatinib	25 mg 100 mg	Tablet	PFI

Monotherapy for the first-line treatment of adult patients with ALK-positive locally advanced (not amenable to curative therapy) or metastatic non–small cell lung cancer (NSCLC).

02475200 02475219	**Lynparza** *(new indication)*	olaparib	100 mg 150 mg	Tablet	AZC

High-risk early breast cancer

For patients with deleterious or suspected deleterious germline BReast CAncer-mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative high-risk early breast cancer if one of the following criteria is met:

• For patients who underwent initial surgery and received adjuvant chemotherapy:

- Those with triple negative breast cancer (TNBC) must have axillary node-positive or axillary node-negative disease with pT ≥ 2 cm, OR
- Those with hormone receptor (HR)-positive, HER2-negative disease must have ≥ 4 involved pathologically confirmed positive lymph nodes

OR

• For patients who underwent neoadjuvant chemotherapy followed by surgery:

- Those with TNBC must have residual invasive breast cancer in the breast and/or resected lymph nodes (non-pCR), OR
- Those with HR-positive, HER2-negative disease must have residual invasive cancer in the breast and/or resected lymph nodes (non-pCR) and a CPS + EG score ≥ 3.

02480018	**Olumiant** *(criteria update, moved from Part 2)*	baricitinib	2mg	Tablet	LIL

For the treatment of patients 18 years of age or older who have moderate to severe active rheumatoid arthritis and have:

(a) failed treatment with at least 3 DMARD therapies, one of which is methotrexate or leflunomide or both, unless intolerance or contraindications to these agents is documented.

(b) tried one combination therapy of DMARDs; and

(c) documented disease activity (such as the number of tender joints, the number of swollen joints, the erythrocyte sedimentation rate or C-reactive protein value).

NOTE: Coverage will be provided only if prescribed by a specialist in rheumatology.

Combined use with other biologic drugs or Janus kinase (JAK) inhibitors will not be reimbursed.

02532611	**Radicava** *(new format)*	edaravone	105 mg/5 ml	Suspension	MIT

For the treatment of amyotrophic lateral sclerosis (ALS). Complete criteria may be obtained from the EDS office at Manitoba Health.

02495155	**Rinvoq**	upadacitinib	15 mg	Tablet	ABV

Rheumatoid Arthritis

For the treatment of patients 18 years of age or older who have moderate to severe active rheumatoid arthritis and have:

(a) failed treatment with at least 3 DMARD therapies, one of which is methotrexate or leflunomide or both, unless intolerance or contraindications to these agents is documented;

(b) tried one combination therapy of DMARDs; and

(c) documented disease activity (such as the number of tender joints, the number of swollen joints, the erythrocyte sedimentation rate or C-reactive protein value).

NOTE: Coverage will be provided only if prescribed by a specialist in rheumatology.

Combined use with other biologic drugs or Janus kinase (JAK) inhibitors will not be reimbursed.

Psoriatic Arthritis

For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented.
One combination therapy of DMARD's must also be tried.
Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.
Request for coverage must be made by a specialist in rheumatology.

Combined use with other biologic drugs or Janus kinase (JAK) inhibitors will not be reimbursed.

02495155 02520893	**Rinvoq**	upadacitinib	15 mg 30 mg	Tablet	ABV

Atopic Dermatitis

For the treatment of refractory moderate to severe[1] atopic dermatitis (AD), in patients aged 12 years and older, only if the following criteria are met:

Initiation Criteria:

- Patient has had an adequate trial[2] (with a documented refractory disease), or was intolerant (with documented intolerance), or is ineligible for each of the following therapies:
    - maximally tolerated medical topical therapies for AD combined with phototherapy (where available); AND
    - maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine).
- The physician must provide the Eczema Area and Severity Index (EASI) score at the time of initial request for reimbursement.

Initial approval: 6 months

Renewal Criteria:

- The physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) 6 months after treatment initiation.
- The physician must provide proof of maintenance of EASI-75 response from baseline for subsequent authorizations.

Renewal approval: 1 year

Request for coverage must be made by, or in consultation with, a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD.

Upadacitinib should not be used in combination with phototherapy, any immunomodulatory agents (including biologics) or other Janus kinase [JAK] inhibitor treatment for moderate to severe AD.

[1] Moderate to severe atopic dermatitis is defined as an EASI score of 16 points or higher.
[2] Adequate trials are defined as:

- Phototherapy – 3 times a week for 12 weeks.
- Methotrexate – 10 to 20mg per week for 12 weeks.
- Cyclosporine – 2.5 to 5mg/kg/day for 12 weeks.
- Mycophenolate mofetil – 1g twice daily for 12 weeks.
- Azathioprine – 1.5 to 2.5mg/kg/day for 12 weeks.

02526204 02526212 02526220	**Teva-Sunitinib**	sunitinib	12.5 mg 25 mg 50 mg	Capsule	TEV

For the treatment of patients with unresectable locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors (pancreatic NET) whose disease is progressive.

For the treatment of metastatic renal cell carcinoma (MRCC) in patients with favourable to intermediate-risk disease.

02487314	**Tremfya**	guselkumab	100 mg/ml	Auto-Injector	JAN
02469758	**Tremfya**	guselkumab	100 mg/ml	Pre-filled Syringe	JAN

Psoriasis

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.

Psoriatic Arthritis

For treatment of patients over 18 years of age who have active psoriatic arthritis who have failed treatment with at least 3 DMARD therapies, one of which is methotrexate and/or leflunomide unless intolerance or contraindications to these agents is documented. One combination therapy of DMARDs must also be tried. Initial application information should include information on disease activity such as the number of tender joints, swollen joints, erythrocyte sedimentation rate and C-reactive protein value.

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

02484137	**Verkazia**	cyclosporine	0.1%	Emulsion	SAI

For the treatment of severe vernal keratoconjunctivitis (VKC) in patients who meet ALL of the following criteria:

- Patient is between 4 and 18 years of age inclusive; AND
- Diagnosis of severe VKC defined as either:
  - Grade 3 (severe) or 4 (very severe) on the Bonini scale, OR
  - Grade 4 (marked) or 5 (severe) on the modified Oxford scale; AND
- Documentation of the baseline severity of signs and symptoms of VKC prior to treatment initiation is provided; AND
- Patient is under the care of a specialist physician with experience in the diagnosis and management of VKC.

Note:
- Patients previously treated with cyclosporine 0.1% but who discontinued treatment upon resolution of VKC signs and symptoms are eligible to reinitiate treatment if signs and symptoms of severe VKC recur and they meet the initiation criteria.

Initial approval period: 6 months

Discontinuation Criteria:
- Treatment should be discontinued if no improvement in signs and symptoms of VKC is observed; OR
- Treatment should be discontinued once signs and symptoms of VKC have resolved.

02487098 02487101 02487128	**Verzenio**	abemaciclib	50 mg 100 mg 150 mg	Tablet	LIL

In combination with endocrine therapy (ET) for the adjuvant treatment of adult patients with hormone receptor (HR)–positive, human epidermal growth factor receptor 2 (HER2)–negative, node-positive early breast cancer at high risk of disease recurrence based on clinicopathological features and a Ki-67 score of at least 20%

02510839	**Vyepti**	eptinezumab	100mg/ml	Solution	LUD

For the prevention of migraine in patients who have a confirmed diagnosis of either:

1. Episodic migraine: headaches for less than 15 days per month for more than 3 months of which at least 4 days per month are with migraine; OR
2. Chronic migraine: headaches for at least 15 days per month for more than 3 months of which at least 8 days per month are with migraine.

Initiation criteria:

- The patient must have experienced an inadequate response[1], intolerance, or contraindication to at least two oral prophylactic migraine medications[2] of different classes; AND
- The patient must be under the care of a physician who has appropriate experience in the management of migraine headaches; AND

- The physician must provide the number of headache and migraine days per month at the time of initial request for reimbursement.

Initial approval duration: 6 months

Initial Renewal criteria:

- Reduction of at least 50% in the average number of migraine days per month compared with baseline.

Renewal duration: 6 months

Subsequent Renewal criteria:

- Maintenance of 50% reduction in the average number of migraine days per month from baseline.

[1]Inadequate response to oral prophylactic therapies is defined as less than a 30% reduction in frequency of headache days to an adequate dose and duration of at least two prophylactic medications, which must be of a different class.

[2]Oral prophylactic medication alternatives include:

- beta blockers
- tricyclic antidepressants
- verapamil or flunarizine
- sodium valproate or divalproex sodium
- topiramate
- gabapentin

02470608	**Xeljanz XR** *(criteria update, moved from Part 2)*	tofacitinib	11 mg	Tablet	PFI

For the treatment of patients 18 years of age or older who have moderate to severe active rheumatoid arthritis and have:

(a) failed treatment with at least 3 DMARD therapies, one of which is methotrexate or leflunomide or both, unless intolerance or contraindications to these agents is documented.

(b) tried one combination therapy of DMARDs; and

(c) documented disease activity (such as the number of tender joints, the number of swollen joints, the erythrocyte sedimentation rate or C-reactive protein value).

NOTE: Coverage will be provided only if prescribed by a specialist in rheumatology.

Combined use with other biologic drugs or Janus kinase (JAK) inhibitors will not be reimbursed.

02527677	**Xpovio**	selinexor	20 mg	Tablet	FTI

In combination with bortezomib and dexamethasone (SVd) for the treatment of patients greater than or equal to 18 years of age who have histologically confirmed multiple myeloma and who have received at least one prior therapy.

New Interchangeable Categories

Alfacalcidol – 0.25mcg – Capsules			**$**	**$ + 5%**
00474517	One Alpha	CAG	0.6038	0.6340
02533316	Sandoz Alfacalcidol	SDZ	0.4313	0.4529

Alfacalcidol – 1 mcg – Capsules			**$**	**$ + 5%**
00474525	One Alpha	CAG	1.8076	1.8980
02533324	Sandoz Alfacalcidol	SDZ	1.2911	1.3557

Amantadine HCL – 10mg/ml - Syrup			**$**	**$ + 5%**
02538601	Odan-Amantadine	ODN	0.0988	0.1037
02022826	PDP-Amantadine	PPI	0.0988	0.1037

Tofacitinib – 10mg			**$**	**$ + 5%**
02480786	Xeljanz	PFI	43.7833	45.9725
02530015	Auro-Tofacitinib	AUP	21.1718	22.2304
02511312	Taro-Tofacitinib	TAR	21.1718	22.2304

New Interchangeable Products

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

Amlodipine – 2.5 mg – Tablets			**$**	**$ + 5%**
02478587	Amlodipine	SAH	0.0767	0.0805

Anastrozole – 1 mg – Tablets			**$**	**$ + 5%**
02529904	Anastrozole	SIP	0.9522	1.0000

Gabapentin – 100 mg – Capsules			**$**	**$ + 5%**
02408880	Mint-Gabapentin	MPH	0.0416	0.0437

Gabapentin – 300 mg – Capsules			**$**	**$ + 5%**
02408899	Mint-Gabapentin	MPH	0.1012	0.1063

Gabapentin – 400 mg – Capsules			**$**	**$ + 5%**
02408902	Mint-Gabapentin	MPH	0.1206	0.1266

Perindopril/Indapamide – 2 mg/0.625 mg - Tablets			**$**	**$ + 5%**
02537990	pms-Perindopril-Indapamide	PMS	0.4227	0.4438

Perindopril/Indapamide – 4 mg/1.25 mg - Tablets			**$**	**$ + 5%**
02538008	pms-Perindopril-Indapamide	PMS	0.2556	0.2684

Perindopril/Indapamide – 8 mg/2.5 mg - Tablets			**$**	**$ + 5%**
02537982	pms-Perindopril-Indapamide	PMS	0.2859	0.3002

Solifenacin – 5 mg – Tablets			**$**	**$ + 5%**
02529696	M-Solifenacin Succinate	MNP	0.3041	0.3193

Solifenacin – 10 mg – Tablets			**$**	**$ + 5%**
02529718	M-Solifenacin Succinate	MNP	0.3041	0.3193

Sunitinib – 12.5 mg – Capsules			**$**	**$ + 5%**
02526204	Teva-Sunitinib	TEV	16.2810	**17.0951

Sunitinib – 25 mg – Capsules			**$**	**$ + 5%**
02526212	Teva-Sunitinib	TEV	32.5618	**34.1899

Sunitinib – 50 mg – Capsules			**$**	**$ + 5%**
02526220	Teva-Sunitinib	TEV	65.1238	**68.3800

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

Interchangeable Product Price Changes

The following changes in price have occurred:					**($)**	**($ + 5%)**
02022826	PDP-Amantadine	amantadine	10mg/ml	Syrup	0.0988	0.1037
02470411	Sandoz Perindopril/ Indapamide	perindopril/ indapamide	2mg/ 0.625mg	Tablet	0.4227	0.4438
02532840	Sandoz Sunitinib	sunitinib	12.5mg	Capsule	16.2810	**17.0951
02532867	Sandoz Sunitinib	sunitinib	25mg	Capsule	32.5618	**34.1899
02532883	Sandoz Sunitinib	sunitinib	50mg	Capsule	65.1238	**68.3800

02524058	Taro-Sunitinib	sunitinib	12.5mg	Capsule	16.2810	**17.0951
02524066	Taro-Sunitinib	sunitinib	25mg	Capsule	32.5618	**34.1899
02524082	Taro-Sunitinib	sunitinib	50mg	Capsule	65.1238	**68.3800

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

Product Deletions

(as identified for deletion in Bulletin #128)

The following products have been deleted.

02393751	Esbriet	pirfenidone	267 mg	Capsule
02190885	Glucobay	acarbose	50 mg	Tablet
02190893	Glucobay	Acarbose	100 mg	Tablet
02261901	Sandoz Diclofenac SR	diclofenac sodium	75 mg	Tablet

Discontinued Products

The following products will be deleted with the next Formulary amendments and will appear as "Product deletions" on Bulletin #130

02464276	Adlyxine	Lixisenatide	10 mcg	Injection
00704423	Androcur-Depot	cyproterone acetate	100 mg	Liquid
02024314	Novolin ge 40/60 Penfill	insulin injection human biosynthetic	100 U/ml	Suspension
02024322	Novolin ge 50/50 Penfill	Insulin injection human biosynthetic	50 U/ml	Suspension
02239372	Zofran ODT	ondansetron	4 mg	Tablet-ODT
02239373	Zofran ODT	ondansetron	8 mg	Tablet-ODT