Health PEI
Provincial Drug Programs
P. O. Box 2000
Charlottetown PE C1A 7N8
1-877-577-3737 (Toll Free on PEI)

Santé Î.-P.-É.
Programmes provinciaux de médicaments
C.P. 2000, Charlottetown
Île-du-Prince-Édouard
Canada C1A 7N8

P.E.I. Pharmacare

Pharmacists' Bulletin

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NEW PRODUCT(S) ADDED TO THE PEI DRUG PROGRAMS FORMULARY
(Effective Date: May 16, 2011)

Product (Generic Name)	Product (Brand Name)	Strength	Dosage Form	DIN	MFR
Abatacept	**ORENCIA**	250 mg	Vial	02282097	BMS
Criteria	For the treatment of **Rheumatoid Arthritis** in patients who: i) Have not responded to a trial of at least 3 months of Leflunomide, **AND** ii) Have not responded to or have had intolerable toxicity to an adequate trial of Methotrexate and at least one of the following DMARDs (disease modifying antirheumatic drugs): IM Gold, Sulfasalazine, Hydroxychloroquine, Azathioprine, Chloroquine, or Penicillamine, **OR** iii) Are intolerant to or have a contraindication to Methotrexate and are refractory to at least two of the following DMARDs (disease modifying antirheumatic drugs): IM Gold, Sulfasalazine, Hydroxychloroquine, Azathioprine, Chloroquine, or Penicillamine, **OR** iv) Are not a candidate for combination DMARD therapy but have had an adequate trial of Methotrexate and at least two of the following DMARDs in sequence: IM Gold, Sulfasalazine, Hydroxychloroquine, Azathioprine, Chloroquine, or Penicillamine. An adequate trial is considered to be 5 months for IM Gold, 6 months for Penicillamine, 4 months for Hydroxychloroquine, and 3 months for all other traditional DMARDs. Unless limited by toxicity, the Methotrexate dosage should be increased up to 25mg/week unless a response is achieved at a lower dose. Maximum adult dose is 500mg for patients < 60kg, 750mg for patients 60 to 100kg, 1000mg for patients > 100kg given at 0, 2, 4, 8 weeks and every 4 weeks thereafter. Pediatric patients 6-17 years of age and < 75kg, coverage is for 10mg/kg based on weight at administration (pediatric patients > 75kg to be treated at adult dose) given at 0, 2, 4, 8 weeks and every 4 weeks thereafter. Approval will not be considered in combination with other biologic agents. **Initial approval** will be for a 6 month period. **Continued coverage** will be for a 12 month period. Renewal of coverage will require reassessment of the patient and submission of a new Special Authorization form. The request for coverage must be made by a rheumatologist or prescriber with a specialty in rheumatology, using the Rheumatoid Arthritis Special Authorization form available from the Drug Programs office or online at http://healthpei.ca/pharmacareforms.				
Program Eligibility	Patients must apply for coverage through the High Cost Drug Program. The patient application is available from the Drug Programs Office or online at http://healthpei.ca/pharmacareforms.				
Acamprosate	**CAMPRAL**	333 mg	Delayed release tablet	02293269	MYL
Criteria	For the maintenance of abstinence from alcohol in patients with a diagnosis of alcohol dependence who have been abstinent for at least four days, and who have contraindications to naltrexone (e.g. currently receiving opioids, acute hepatitis or liver failure). Treatment with acamprosate should be part of a comprehensive management plan that includes counseling. The maximum treatment duration is 12 months.				
Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				

Ambrisentan		**VOLIBRIS**	5 mg 10 mg	Tablet Tablet	02307065 02307073	GSK
	Criteria	**GENERAL COVERAGE CRITERIA** Coverage is limited to the treatment of Idiopathic Pulmonary Arterial Hypertension (IPAH) and Pulmonary Arterial Hypertension (PAH) secondary to scleroderma, congenital heart disease or HIV. Coverage will only be approved in a step-wise manner of Sildenafil to Bosentan or Ambrisentan to Flolan (see treatment algorithm below). Coverage of the next medication in the sequence will only be considered where a patient has failed or was intolerant to therapy with the previous medication or where the previous medication is contraindicated. **TREATMENT ALGORITHM**: **Step 1** - Sildenafil (functional class III) **Step 2** - Bosentan **OR** Ambrisentan (functional class III and IV) **Step 3** - Epoprostentol Maximum dose is up to 10 mg once daily. Coverage will only be provided for one medication at a time. There will be no coverage allowed for tapering off or overlap of medications. Coverage will be based upon a monthly supply of mediation with no more than one prescription for a given medication and strength being covered in a 30-day period. Coverage must be requested and all medications prescribed by a Pulmonary Arterial Hypertension (PAH) specialist. Diagnosis of pulmonary arterial hypertension (PAH) must be confirmed by right heart catheterization.				
	Program Eligibility	Patients must apply for coverage through the High Cost Drug Program. The patient application is available from the Drug Programs Office or online at http://healthpei.ca/pharmacareforms.				
Alendronate & Cholecalciferol		**FOSAVANCE**	70 mg/5600 unit	Tablet	02314940	MSD
	Criteria	For the treatment of osteoporosis in patients with a documented fragility fracture **OR** For use in patients without documented fracture but with a high 10-year fracture risk, determined using fracture risk tables, (a copy of the bone density report, including the T-score, supporting the diagnosis must accompany the Special Authorization) **OR** For prophylaxis of corticosteroid induced osteoporosis in patients who will be or have been on systemic corticosteroid therapy for ≥ 3 months.				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Brinzolamide & Timolol		**AZARGA**	1 %/0.5 %	Ophthalmic suspension	02331624	ALC
	Criteria	Open benefit				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Buprenorphine & Naloxone		**SUBOXONE**	2 mg/0.5 mg 8 mg/2 mg	Sublingual tablet Sublingual tablet	02295695 02295709	MSD
	Criteria	For the treatment of opioid dependence for patients in whom methadone is contraindicated (e.g. patients at high risk of, or with QT prolongation, or hypersensitivity to methadone). Commonly reported adverse effects associated with methadone therapy (eg. sweating, constipation, insomnia, etc.) will not be considered to be hypersensitivity.				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Betamethasone Dipropionate & Calcipotriol		**XAMIOL**	50 mcg/0.5 mg/gm	Topical gel	02319012	LEO
	Criteria	For the treatment of patients with scalp psoriasis who have failed a trial with a topical steroid alone **AND** who have failed a trial with a topical steroid **and** calcipotriol together.				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Carbidopa & Levodopa & Entacapone		**STALEVO 50** **STALEVO 100** **STALEVO 150** **STALEVO 75** **STALEVO 125**	12.5/50/200 mg 25/100/200 mg 37.5/150/200 mg 18.75/75/200 mg 31.25/125/20mg	Tablet Tablet Tablet Tablet Tablet	02309533 02305941 02305968 02337827 02337835	NVR
	Criteria	For the treatment of Parkinson's disease in patients who are not well controlled and are experiencing significant "wearing off" symptoms despite optimal therapy with levodopa/carbidopa and are currently stablilized on levodopa/carbidopa and entacapone separately.				

	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs

Darifenacin		**ENABLEX**	7.5 mg 15 mg	Extended release tablet Extended release tablet	02273217 02273225	NVR
	Criteria	For the treatment of over-active bladder (not stress incontinence) in patients who cannot tolerate or have an insufficient response to an adequate trial (e.g. 3 months) of immediate release oxybutynin.				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Gatifloxacin		**ZYMAR**	0.3 %	Ophthalmic drops	0 2257270	ALL
	Criteria	For the treatment/prevention of bacterial conjunctivitis associated with eye surgery.				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Glulisine		**APIDRA**	100 unit/ml 100 unit/ml	Vial Prefilled pen	02279460 02294346	AVN
	Criteria	Open benefit				
	Program Eligibility	Diabetes Control Program				
Golimumab		**SIMPONI**	50 mg/0.5 ml 50 mg/0.5 ml	Syringe Auto-injector	02324776 02324784	MSD

	Criteria	Approval will not be considered in combination with other biologic agents. **For the treatment of Rheumatoid Arthritis in patients who:** i) Have not responded to a trial of at least 3 months of Leflunomide, **AND** ii) Have not responded to or have had intolerable toxicity to an adequate trial of Methotrexate and at least one of the following DMARDs (disease modifying antirheumatic drugs): IM Gold, Sulfasalazine, Hydroxychloroquine, Azathioprine, Chloroquine, or Penicillamine, **OR** iii) Are intolerant to or have a contraindication to Methotrexate and are refractory to at least two of the following DMARDs (disease modifying antirheumatic drugs): IM Gold, Sulfasalazine, Hydroxychloroquine, Azathioprine, Chloroquine, or Penicillamine, **OR** iv) Are not a candidate for combination DMARD therapy but have had an adequate trial of Methotrexate and at least two of the following DMARDs in sequence: IM Gold, Sulfasalazine, Hydroxychloroquine, Azathioprine, Chloroquine, or Penicillamine. An adequate trial is considered to be 5 months for IM Gold, 6 months for Penicillamine, 4 months for Hydroxychloroquine, and 3 months for all other traditional DMARDs. Unless limited by toxicity, the Methotrexate dosage should be increased up to 25mg/week unless a response is achieved at a lower dose. Maximum adult dose is 50mg once monthly. **Initial approval** will be for a 6 month period. **Continued coverage** will be for a 12 month period. The request for coverage must be made by a rheumatologist or prescriber with a specialty in rheumatology, using the Rheumatoid Arthritis Special Authorization form available from the Drug Programs office or online at http://healthpei.ca/pharmacareforms. **For the treatment of patients with moderate to severe Ankylosing Spondylitis** (Bath AS Disease Activity Index (BASDAI) score ≥4 on 10 point scale who: a) Have axial symptoms* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation or in whom NSAIDs are contraindicated **OR** b) Have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD. *Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease, do not require a trial of NSAIDs alone. Requests for renewal must include information showing the beneficial effects of the treatment, specifically: a) A decrease of at least two points on the BASDAI scale, compared with pre-treatment score **OR** b) Patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as Health Assessment Questionnaire (HAQ) or ability to return to work). Maximum adult dose is 50mg once monthly. **Initial approval** will be for 6 month period. **Continued coverage** will be for a 6month period. The request for coverage must be made by a rheumatologist or prescriber with a specialty in rheumatology, using the Ankylosing Spondylitis Special Authorization form available from the Drug Programs office or online at. http://healthpei.ca/pharmacareforms. **For the treatment of active Psoriatic Arthritis in patients who meet the following criteria;** a) Have at least three active and tender joints, **AND** b) Have not responded to an adequate trial with two DMARDs or have an intolerance or contraindication to DMARDs. Maximum adult dose is 50mcg once monthly. **Initial approval** will be for a 4 month period. Continued coverage will be for a 12 month period and reassessment for coverage is dependent on patient achieving an improvement in symptoms of at least 20% (ACR20) or response using the Psoriatic Arthritis Response Criteria. The request for coverage must be made by a rheumatologist or prescriber with a specialty in rheumatology, using the Psoriatic Arthritis Special Authorization form available from the Drug Programs office or online at http://healthpei.ca/pharmacareforms.				
	Program Eligibility	Patients must apply for coverage through the High Cost Drug Program. The patient application is available from the Drug Programs Office or online at http://healthpei.ca/pharmacareforms.				
Moxifloxacin		**VIGAMOX**	0.5 %	Ophthalmic drops	0 2252260	ALC
	Criteria	For the treatment/prevention of bacterial conjunctivitis associated with eye surgery.				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Olmesartan		**OLMETEC**	20 mg 40 mg	Tablet Tablet	02318660 02318679	MSD
	Criteria	Open benefit				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Olmesartan & Hydrochlorothiazide		**OLMETEC PLUS**	20/12.5 mg 40/12.5 mg 40/25 mg	Tablet Tablet Tablet	02319616 02319624 02319632	MSD

	Criteria	Open benefit				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Quinagolide		**NORPROLAC**	75 mcg 150 mcg	Tablet Tablet	02223767 02223775	FEI
	Criteria	For the treatment of patients with hyperprolactinemia who have failed or are intolerant to bromocriptine.				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Rituximab		**RITUXAN**	10 mg/ml	Vial	0 2241927	HLR
	Criteria	For the treatment of adult patients with severe active **Rheumatoid Arthritis** who have failed to respond to an adequate trial with an anti-TNF agent. a) Rituximab will NOT be considered in combination with other biologic agents. b) Approval for re-treatment with rituximab will only be considered for patients who have achieved a response, followed by a subsequent loss of effect and, after an interval of no less than six months from the previous dose. Maximum adult dose is 1000 mg by IV infusion followed two weeks later by the second 1000 mg IV infusion. The request for coverage must be made by a rheumatologist or prescriber with a specialty in rheumatology, using the Rheumatoid Arthritis Special Authorization form available from the Drug Programs office or online at http://healthpei.ca/pharmacareforms.				
	Program Eligibility	Patients must apply for coverage through the High Cost Drug Program. The patient application is available from the Drug Programs Office or online at http://healthpei.ca/pharmacareforms.				
Rivaroxaban		**XARELTO**	10 mg	Tablet	02316986	BAY
	Criteria	For the prophylaxis of venous thromboembolism (VTE) following total knee replacement surgery for up to 14 days after surgery or total hip replacement surgery for up to 35 days after surgery as an alternative to low molecular weight heparins. The maximum dose of rivaroxaban that will be reimbursed is 10 mg daily.				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Solifenacin		**VESICARE**	5 mg 10 mg	Tablet Tablet	02277263 02277271	AST
	Criteria	For the treatment of over-active bladder (not stress incontinence) in patients who cannot tolerate or have an insufficient response to an adequate trial (e.g. 3 months) of immediate release oxybutynin.				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Somatropin		**OMNITROPE**	5 mg/1.5 ml 10 mg/1.5 ml	Cartridge Cartridge	02325063 02325071	SDZ
	Criteria	Open benefit				
	Program Eligibility	Growth Hormone Drug Program				
Tacrolimus		**ADVAGRAF**	0.5 mg 1 mg 3 mg 5 mg	ER capsule ER capsule ER capsule ER capsule	02296462 02296470 02331667 02296489	AST
	Criteria	Open benefit				
	Program Eligibility	Transplant Drug Program				
Tacrolimus		**PROTOPIC**	0.1 %	Ointment	02244148	AST
	Criteria	For the intermittent use in adults with moderate to severe atopic dermatitis who have failed or are intolerant to a site appropriate strength of corticosteroid therapy (i.e. low potency on face versus intermediate to high potency for trunk and extremities).				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Testosterone		**ANDROGEL**	25 mg/2.5 gm 50 mg/5 gm	Transdermal gel Transdermal gel	02245345 02245346	ABB

	Criteria	For the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of; **Primary -** Cryptorchidism, Klinefelter's, orichidectomy, and other established causes. **Secondary -** Pituitary-hypothalamic injury due to tumors, trauma, radiation. Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate biochemical tests before initiating any testosterone therapy. Limited to 5 g/day gel. **Older males with non-specific symptoms of fatigue, malaise or depression who have low testosterone (T) levels do not satisfy these criteria.**				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Testosterone	**TESTIM**	50 mg/5 gm	Transdermal gel	02280248	PAL
	Criteria	For the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of; **Primary -** Cryptorchidism, Klinefelter's, orichidectomy, and other established causes. **Secondary -** Pituitary-hypothalamic injury due to tumors, trauma, radiation. Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate biochemical tests before initiating any testosterone therapy. Limited to 5 g/day gel. **Older males with non-specific symptoms of fatigue, malaise or depression who have low testosterone (T) levels do not satisfy these criteria.**				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs				
Tinzaparin	**INNOHEP**	2500unit/0.25 ml 3500unit/0.35 ml 4500unit/0.45 ml 10000unit/0.5 ml 14000unit/0.7 ml 18000unit/0.9 ml 10000unit/ml 20000unit/ml	Syringe Syringe Syringe Syringe Syringe Syringe Multi dose vial Multi dose vial	02229755 02358158 02358166 02231478 02358174 02358182 02167840 02229515	LEO
	Criteria	For the acute treatment of deep vein thrombosis (DVT) and/or pulmonary embolism (PE) for a maximum of 10 days. For prophylaxis of venous thromboembolism (VTE) in hip replacement and hip fracture surgery, approval is limited to a maximum of 35 days. For prophylaxis of venous thromboembolism (VTE) in knee replacement surgery, approval is limited to a maximum of 10 days. For prophylaxis of venous thromboembolism (VTE) in high risk surgery, approval is limited to maximum of 10 days.				
	Program Eligibility	Family Health Benefit, Financial Assistance, Nursing Home and Seniors Drug Programs The request for coverage must be made using the Low Molecular Weight Heparin Special Authorization form available from the Drug Programs office or online at http://healthpei.ca/pharmacareforms.				

NON-INSURED PRODUCTS

The following product(s) were recently reviewed by the Canadian Expert Drug Advisory Committee (CEDAC) or the Joint Oncology Drug Review (JODR) process and there was a "**DO NOT LIST**" recommendation for provincial public drug programs. As a result the following medications will **NOT** be listed as insured benefits under the PEI Drug Programs **NOR** will they be considered for coverage through the Special Authorization request process.

Paliperidone Palmitate	**INVEGA SUSTENNA**	50 mg/0.5 ml 75 mg/0.75 ml 100 mg/1 ml 150 mg/1.5 ml	Prefilled syringe Prefilled syringe Prefilled syringe Prefilled syringe	02354217 02354225 02354233 02354241	JAN
	Indication	Schizophrenia			
	CEDAC Decision Highlights	Paliperidone palmitate was reported to be non-inferior to risperidone long-acting injection. However, at dose equivalency, paliperidone palmitate would be more costly			

IMPORTANT NOTICES

To secure blood glucose strip coverage for persons registered under the Diabetes Program who use an insulin product not covered by PEI Pharmacare, please fax the request to the Drug Program office. You may also contact the Helpdesk to log the ticket. Note: the client must have had a prescription for insulin filled in the last 150 days to be eligible for blood glucose strip coverage, **AND** be registered under the Diabetes Program.

The Helpdesk has received a number of calls to have blood glucose strips set up for clients who are on Victoza. Because Victoza is not an insulin product, clients using this medication are not eligible for coverage of blood glucose strips under the Diabetes Program.