

Quarterly Report on Completed Drug Submission Reviews

Last Updated Jan 2024

The *Quarterly Report on Completed Drug Submission Reviews* report is divided into three reports for each year¹:

- 1. The *Type, Timelines and Number of Completed Drug Submission Reviews, by Quarter* reports provide detailed information on the type of drug review, the target and actual timelines for each review, the total number of reviews, and the percentage of reviews that are completed and result in a PharmaCare coverage decision within the specific timeline for the given year.
- 2. The *Drug Review Decisions Summary* reports provide detailed information on the Ministry's coverage decision for each drug that PharmaCare has reviewed in the given year.
- 3. The *Patient and Caregiver Input Summary* provides information on the number of responses to the Ministry's call for patient, caregiver and patient group input for each drug that PharmaCare has reviewed in the given year. Responses are collected via the PharmaCare <u>Your Voice</u> website.

Contents

2023 Reports	2
Type, Timelines, and Number of Completed Drug Submission Reviews, by Quarter	2
Drug Review Decisions Summary	3
Patient and Caregiver Input Summary	8

2023 Reports

Type, Timelines, and Number of Completed Drug Submission Reviews, by Quarter

Reporting Period	Review Type ¹	Target Timeline (months)	Reviews Completed ²	Avg.	ctual Review (months) <i>Min.</i>		Reviews Meeting Target Timeline (%)
	Priority	6	0	N/A	N/A	N/A	N/A
	Standard	9	5	1.98	1	3.5	100%
Q1 2023	Priority Complex	9	0	N/A	N/A	N/A	N/A
	Complex	12	11	23.3	14	30	0%
	Other ³	N/A	0	N/A	N/A	N/A	N/A
	Priority	6	0	N/A	N/A	N/A	N/A
	Standard	9	6	6.5	1.8	9.5	83%
Q2	Priority Complex	9	0	N/A	N/A	N/A	N/A
2023	Complex	12	12	22.5	11	35.6	0%
	Other	N/A	1	6	6	6	6
	Priority	6	0	N/A	N/A	N/A	N/A
	Standard	9	6	6.9	1.2	9.5	83%
Q3 2023	Priority Complex	9	0	N/A	N/A	N/A	N/A
2023	Complex	12	7	20.2	11.9	35.5	14.3%
	Other	N/A	2	N/A	N/A	N/A	N/A
	Priority	6	0	N/A	N/A	N/A	N/A
04	Standard	9	5	11.9	1.8	23.9	20%
Q4 2023	Priority Complex	9	0	N/A	N/A	N/A	N/A
2020	Complex	12	5	15.4	0.65	30.3	20%
	Other	N/A	5	N/A	N/A	N/A	N/A
	Priority	6	0	N/A	N/A	N/A	N/A
	Standard	9	17	5.3	1	9.5	94%
2022	Priority Complex	9	0	N/A	N/A	N/A	N/A
2023 YTD Total	Complex	12	30	22	11	35.6	3%
	Other	N/A	3	N/A	N/A	N/A	N/A
	Submissions with Timelines₅ ⁴	6-12	47	17.2	1	35.6	34%

¹ Review types are defined in "<u>The Drug Review Process in B.C. – Detailed</u>" on the PharmaCare website.

² A submission review is complete on the date of the formulary decision or the coverage effective date.

³ The 'Other' category covers submissions not subject to target timelines.

Drug Review Decisions Summary

	Generic Name	Trade Name	Indication	Submission Type	Decision Date	Decision
	dapagliflozin	Forxiga	HFrEF & T2DM	Criteria Modification	05-Jan-23	Regular Benefit
	empagliflozin	Jardiance	Type 2 Diabetes mellitus	Criteria Modification	05-Jan-23	Limited Coverage
	semaglutide	Wegovy	weight management	Criteria Modification	05-Jan-23	Limited Coverage
	insulin aspart biosimilar	Kirsty	Diabetes	Biosimilar	24-Jan-23	Regular Benefit
	bimekizumab	Bimzelx	Psoriasis, moderate to severe plaque	New Submission	31-Jan-23	Limited Coverage
	fostamatinib	Tavalisse	Chronic immune thrombocytopenia	New Submission	31-Jan-23	Non- Benefit
	semaglutide	Rybelsus	Diabetes mellitus, type 2	New Submission	31-Jan-23	Non- Benefit
	eculizumab	Soliris	Neuromyelitis optica spectrum disorder	New Indication	10-Feb-23	Non- Benefit
Q1	eculizumab	Soliris	Myasthenia Gravis (gMG), adults	New Indication	10-Feb-23	Non- Benefit
	incobotulinumtoxin A	Xeomin	Chronic sialorrhea associated with neurological disorders	New Submission	14-Feb-23	Non- Benefit
	amlodipine liquid Line Extension	PDP- amlodipine	Hypertension / angina	Line Extension	28-Feb-23	Limited Coverage
	glycopyrrolate	Cuvposa	chronic severe drooling, neurologic (pediatric)	New Submission	28-Feb-23	Non- Benefit
	voretigene neparvovec	Luxturna	Vision loss, inherited retinal dystrophy	New Submission	28-Feb-23	EDRD (case by case)
	luspatercept	Reblozyl	Myelodysplastic syndromes- associated anemia	New Submission	14-Mar-23	Non- Benefit
	luspatercept	Reblozyl	beta-thalassemia associated anemia	New Submission	14-Mar-23	Limited Coverage
	amifampridine	Ruzurgi	Lambert-Eaton myasthenic syndrome	New Submission	28-Mar-23	Limited Coverage

	sebelipase alfa	Kanuma	lysosomal acid lipase deficiency	New Submission	5-Apr-23	EDRD (case by case)
	mesalamine oral delayed release tablet 500 mg	Mezera	for active or moderate ulcerative colitis	Line Extension	11-Apr-23	Non- Benefit
	galcanezumab	Emgality	Prevention of migraine	New Submission	11-Apr-23	Limited Coverage Criteria
	ustekinumab	Stelara/Stelara IV	ulcerative colitis	New Indication	17-Jan-23	Non- Benefit
	tretinoin gel Line Extension	Retin-A Micro	Acne	New Submission	March 7, 2023 (non benefit)	Non- Benefit
	mecasermin	Increlex	Severe primary insulin-like growth factor-1 deficiency	New Submission	April 27, 2023	EDRD (case by case)
	somatrogon	Ngenla	Growth hormone deficiency	New Submission	May 2, 2023	Non- Benefit
	safinamide	Onstryv	Parkinson's disease	New Submission	May 4, 2023	Non- Benefiit
	cariprazine	Vraylar	Bipolar disorder	New Submission	May 4, 2023	Non- Benefit
	cariprazine	Vraylar	Schizophrenia	New Submission	May 4, 2023	Non- Benefit
Q2	tafamidis	Vyndamax	transthyretin- mediated amyloidosis	Line Extension	May 11, 2023	EDRD (case by case)
	triheptanoin	Dojolvi	Long-chain fatty acid oxidation disorders	New Submission	May 23, 2023	EDRD (case by case)
	insulin glargine	Semglee	Insulin biosimilar	New Submission	May 25, 2023	Limited Coverage
	caplacizumab (EDRD)	Cablivi	Acquired thrombotic thrombocytopenic purpura (aTTP)	Resubmission	May 26, 2023	EDRD (case by case)
	mesalamine	Octasa	ulcerative colitis	Line Extension	May 30, 2023	Non- Benefit
	prasterone	Intrarosa	Postmenopausal vulvovaginal atrophy	New Submission	May 30, 2023	Non- Benefit
	ospemifene	Osphena	Postmenopausal dyspareunia, vaginal dryness	New Submission	May 30, 2023	Non- Benefit
	enoxaparin sodium (Biosimilar)	Elonox / Elonox HP	deep vein thrombosis	Biosimilar	June 1, 2023	Limited Coverage

	Givosiran	Givlaari	Acute Hepatic Porphyria	New Submission	June 22, 2023	EDRD (case by case)
	enoxaparin sodium (Biosimilar)	Elonox / Elonox HP	deep vein thrombosis	Biosimilar	June 1, 2023	Limited Coverage Criteria
	givosiran	Givlaari	Treatment of acute hepatic porphyria (AHP) in adults	New Submission	June 22, 2023	Non- Benefit, Exceptional Case by Case
	somatropin (line extension)	Norditropin FlexPro	Growth hormone deficiency	Line Extension	July 4, 2023	Limited Coverage Criteria
	Icosapent ethyl	Vascepa	Ischemic events in statin-treated patients	New Submission	July 6, 2023	Non- Benefit
	estradiol and progesterone	Bijuva	Vasomotor symptoms associated with menopause	New Submission	July 6, 2023	Non- Benefit
Q3	sodium phenylbutyrate and ursodoxicoltaurine (EDRD)	Albrioza	Amyotrophic lateral sclerosis (ALS)	New Submission	July 19, 2023	Limited Coverage Criteria
	pancrelipase	Pancrease	Treatment of pancreatic insufficiency attributed to cystic fibrosis, chronic pancreatitis, or any other medically defined pancreatic disease that might require pancreatic enzyme therapy.	Line Extension	July 25, 2023	Non- Benefit
	Flash Glucose Monitoring System	Freestyle Libre	Diabetes - Ministry Initiated	Resubmission	August 1, 2023	Limited Coverage
	pitolisant hydrochloride	Wakix	Narcolepsy	New Submission	August 15, 2023	Non- Benefit

	dexamethasone intravitreal implant (CADTH resubmission)	Ozurdex	Diabetic Macular Edema	Resubmission	August 17, 2023	Non- Benefit - EDRD
	onabotulinumtoxin A (50, 100, 200 unit vial)	Botox	Various	Ministry Initiated	August 17, 2023	Completed
	edaravone oral (EDRD)	Radicava	Amyotrophic lateral sclerosis (ALS)	New Submission	August 18, 2023	Limited Coverage EDRD
	amifampridine phosphate	Firdapse	Lambert-Eaton Myasthenic Syndrome, adults	New Submission	September 7, 2023	Limited Coverage
	ravulizumab	Ultomiris	Paroxysmal nocturnal hemoglobinuria	New Submission	September 22, 2023	Non- Benefit
	ravulizumab (EDRD)	Ultomiris	Atypical hemolytic uremic syndrome	New Submission	September 22, 2023	Non- Benefit
	mepolizumab/benralizumab	Nucala/Fasenra	Asthma: Modification of LC criteria	Modification of Coverage	17-Oct-23	Limited Coverage Criteria
	dupilumab	Dupixent	Asthma (age 6 to <12 years, add on therapy)	New Submission	October 17, 2023	Limited Coverage Criteria
Q4	avalglucosidase alfa	Nexviazyme	Pompe disease	New Submission	October 30, 2023	Non- Benefit
	satralizumab	Enspryng	Neuromyelitis optica spectrum disorder	New Submission	November 1, 2023	Limited Coverage Criteria
	Ministry initiated: rituximab and tocilizumab	Multiple biosimilars	NMOSD	Ministry Initiated	November 1, 2023	Limited Coverage Criteria
	Dexcom Continuous Glucose Monitor	Dexcom G7	Diabetes	New Submission	November 7, 2023	Limited Coverage Criteria

ruxolitinib	Jakavi	Graft versus host disease (acute)	New Submission	November 23, 2023	Limited Coverage Criteria
ruxolitinib	Jakavi	Graft versus host disease (chronic)	New Submission	November 23, 2023	Limited Coverage Criteria
guselkumab injection	Tremfya	Psoriatic Arthritis	New Submission	November 28, 2023	Non- Benefit
rivaroxaban	Xarelto	Multiple Indications LC to RB	Ministry Initiated	07-Dec-23	Regular benefit
romosozumab	Evenity	Osteoporosis, postmenopausal women	New Submission	December 14, 2023	Limited Coverage
tezepelumab	Tezspire	Asthma	New Submission	December 14, 2023	Limited Coverage
elexacaftor/tezacaftor/ivacaftor	Trikafta	Cystic fibrosis, F508del CFTR mutation, 2 years and older	Modification of Coverage	December 14, 2023	EDRD
adalimumab	Yuflyma	Multiple Indications	Biosimilar	December 19, 2023	Limited Coverage
adalimumab	Hadlima	Multiple Indications	Biosimilar	December 19, 2023	Limited Coverage

Patient and Caregiver Input Summary

Dro	Drug Details			Responses t	o calls for input
Generic Name	Trade Name	Indication	Patient	Caregiver	Patient Group
lurasidone	Latuda and generics	bipolar 1 disorder	0	0	0
pegcetacoplan	Empaveli	Paroxysmal nocturnal hemoglobinuria (PNH)	0	0	2
ferumoxytol	Feraheme	Iron deficiency anemia	0	0	0
difelikefalin	Korsuva	Chronic Kidney Disease associated pruritus	0	0	0
mavacamten	Camzyos	Obstructive hypertrophic cardiomyopathy	1	0	1
deucravacitinib	Sotyktu	Plaque psoriasis, moderate to severe	0	0	1
risankizumab	Skyrizi	Crohn's disease	0	0	2
ravulizumab	Ultomiris	AChR antibody- positive generalized Myasthenia Gravis	0	0	0
avacopan	Tavneos	Antineutrophil cytoplasmic antibody-associated vasculitis	0	2	1
vericiguat	Verquvo	Heart failure	0	0	1
upadacitinib	Rinvoq	Ankylosing spondylitis	0	0	1
palovarotene	Sohonos	Fibrodysplasia Ossificans Progressiva	0	0	1
selumetinib	Koselugo	Neurofibromatosis type 1	5	6	1
foslevodopa foscarbidopa	ТВС	Parkinson's disease	0	0	1
atogepant	Qulipta	Prevention of episodic migraine	28	3	1

roflumilast	Zoryve	Plaque psoriasis	1	0	1 (joint submission of three patient groups)
cenobamate	ТВС	Epilepsy, partial onset seizures	0	0	0
adalimumab	biosimilars (TR)	Non-infectious uveitis	0	0	0
mirikizumab	ТВС	ulcerativr colitis	3	0	2
setmelanotide	Imcivree	Bardet-Biedly syndrom-associated obesity	0	0	1
dupilumab	Dupixent Peds	atopic dermatitis, ages 6 months to 12 years	1	4	1
elexacaftor/tezacaftor/ivacaftor and ivacaftor	Trikafta	Cystic fibrosis, 2 to 5 years	0	1	1
maralixibat	Livmarli	Alagille syndrome- associated cholestatic pruritus	0	0	0
efgartigimod alfa	Vyvgart	generalized myasthenia gravis (gMG)	0	0	0
evinacumab	ТВС	Homozygous familial hypercholesterolemia (HoFH)	20	0	0
somapacitan	Sogroya	growth hormone deficiency	0	0	0
secukinumab	Cosentyx	Hidradenitis suppurativa	0	0	0
tralokinumab	Adtralza	atopic dermatitis	0	0	1
avatrombopag	Doptelet	chronic immune thrombocytopenia (ITP)	0	0	0
upadacitinib	Rinvoq	Crohn's disease	0	0	2
odevixibat	Bylvay	progressive familial intrahepatic Cholestasis (PFIC)	0	0	0
vutrisiran	Amvuttra	hereditary transthyretin mediated amyloidosis	0	0	0

clascoterone	Winlevi	acne vulgaris	1	0	2
metreleptin	Myalepta	leptin deficiency in lipodystrophy	0	0	0
belumosudil	Rezurock	chronic graft-versus- host disease (cGVHD)	0	0	1
nirmatrelvir-ritonavir	Paxlovid	COVID-19 in patients at high risk for progression to severe	13	2	2
fidanacogene elaparvovec	ТВС	moderately severe to severe hemophilia B	0	0	1