

Quarterly Report on Completed Drug Submission Reviews

Last Updated June 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.

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2024 Reports

Reporting Period	Review Type ¹	Target Timeline Completed ²		A	ctual Review (months)		Reviews Meeting
Tenou		(months)	completed	Avg.	Min.	Max.	Target Timeline (%)
	Priority	6	0	N/A	N/A	N/A	N/A
	Standard	9	4	9.07	1.75	14.13	50%
Q1 2024	Priority Complex	9	0	N/A	N/A	N/A	N/A
2024	Complex	12	3	12.3	11.49	13.79	66%
	Other ³	N/A	3	N/A	N/A	N/A	N/A
	Priority	6	0	N/A	N/A	N/A	N/A
	Standard	9	4	7.4	1.55	12.49	75%
Q2 2024	Priority Complex	9	0	N/A	N/A	N/A	N/A
2024	Complex	12	6	16.21	8.92	27.79	50%
	Other	N/A	0	N/A	N/A	N/A	N/A
	Priority	6	0	N/A	N/A	N/A	N/A
	Standard	9	8	5.3	1	9.5	94%
2024	Priority Complex	9	0	N/A	N/A	N/A	N/A
2024 YTD Total	Complex	12	9	22	11	35.6	3%
TDTOLA	Other	N/A	3	N/A	N/A	N/A	N/A
	Submissions with Timelines₅ ⁴	6-12	17	11.85	1.75	27.49	58%

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

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.

Generic Name Trade Name Indication **Submission Type Decision Date** Decision Limited ulcerative colitis **New Submission** January 16, 2024 ozanimod Zeposia Coverage Benefit **Regular Benefit** riluzole rilutek ALS Generic February 1, 2024 - EDRD semaglutide Limited Type 2 Diabetes Line Extension February 6, 2024 Ozempic 0.68 mg/mL Coverage LDL - Reverse Limited Icosapent Vascepa decision from NB to Ministry Initiated February 6, 2024 Coverage LC Chronic Kidney Limited finerenone Kerendia New Submission February 27, 2024 Coverage Disease Antineutrophil Q1 cytoplasmic Tavneos **New Submission** February 27, 2024 Non-Benefit avacopan antibody-associated vasculitis Paroxysmal nocturnal Case by Case pegcetacoplan Empaveli **New Submission** March 6, 2024 hemoglobinuria EDRD Limited lurasidone Latuda **Bipolar** depression Ministry-initiated March 7, 2024 Coverage lemborexant Dayvigo Insomnia **New Submission** March 14, 2024 Non-Benefit transfusional iron overload due to deferiprone Ferriprox New Submission March 14, 2024 Non-Benefit sickle cell disease or other anemias topical treatment of acne vulgaris in Modification of Limited tazarotene Arazlo April 9, 2024 patients 10 years of Coverage Coverage age and older. anti-acetylcholine receptor (AChR) antibody-positive ravulizumab Ultomiris New Submission April 17, 2024 Non-Benefit generalized Myasthenia Gravis Q2 (gMG) Limited eptinezumab Vyepti Migraine **New Submission** April 23, 2024 Coverage Chronic Kidney difelikefalin April 30, 2024 Non-Benefit Korsuva Disease associated New Submission pruritus for the prevention filgrastim Limited and treatment of Biosimilar May 14, 2024 Nypozi injection Coverage neutropenia

2024 Drug Review Decisions Summary

estradiol	Imvexxy	Dyspareunia	New Submission	May 14, 2024	Regular Benefit
nirmatrelvir/ ritonavir	Paxlovid	Mild-to-moderate COVID-19, treatment	New Submission	May 28, 2024	Plan Z (Assurance Plan) benefit
ustekinumab biosimilar	Jamteki	Plaque Psoriasis, Psoriatic Arthritis	Biosimilar	May 30, 2024	Limited Coverage
risankizumab	Skyrizi	Crohns's Disease	New Submission	May 30, 2024	Limited Coverage
budesonide foam	Uceris	for active or moderate distal ulcerative colitis	Line Extension	June 18, 2024	Regular Benefit
Etanercept biosimilar	Rymti	Multiple	Biosimilar	June 25, 2024	Limited Coverage

	Drug Details		Patient Re	Patient Responses to calls for input		
Generic Name	Trade Name	Indication	Patient	Caregiver	Patient Group	
inclisiran	Leqvio	heterozygous familial hypercholesterolemia (HeFH	57	0	0	
inclisiran	Leqvio	non-familial hypercholesterolemia (nFH) with atherosclerotic cardiovascular disease (ASCVD)	22	3	0	
infliximab	Remsima	Crohn's disease	1	0	1	
infliximab	Remsima	ulcerative colitis	1	0	1	
cannabidiol	Epidiolex	seizures associated with Tuberous sclerosis complex (TSC)	0	0	0	
cannabidiol	Epidiolex	Seizures associated with Lennox-Gastaut Syndrome (LGS)	0	0	0	
cannabidiol	Epidiolex	Seizures associated with Dravet syndrome (DS)	0	0	0	
bimekizumab	Bimzelx	Active ankylosing spondylitis	0	0	2 (1 is joint submission from 4 groups)	
bimekizumab	Bimzelx	active psoriatic arthritis (PsA)	0	0	2	
glecaprevir- pibrentasvir	Maviret	chronic hepatitis C virus (HCV) infection in pediatric patients 3 years of age and older and weighing at least 12 kg.	0	2	1	
risperidone	ТВС	schizophrenia in adults	0	0	0	
lebrikizumab	твс	atopic dermatitis (AD)	1	0	1	
insulin icodec	Awiqli	type 2 diabetes	0	0	2	
evolocumab	Repatha	primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH) and atherosclerotic cardiovascular disease (ASCVD).	4	0	0	

2024 Patient and Caregiver Input Summary

		venous thromboembolic events (VTE) and prevention of VTE recurrence in term neonates, infants and toddlers, and children and adolescents aged less than			
rivaroxaban	Xarelto	18 years	0	0	0
atogepant	Qulipta	chronic migraine prevention X-linked	6	1	0
burosumab	Crysvita	hypophosphatemia in adults	0	0	0
etrasimod	Velsipity	Ulcerative colitis (UC)	0	0	1
remdesivir	Velklury		8	2	1
fidaxomicin	Dificid	First line treatment of C. difficile infection	1	0	1

2023 Reports

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

Reporting Period	Review Type ¹	Target Timeline	Reviews Completed ²	A	ctual Review (months)		Reviews Meeting
i chou		(months)	completed	Avg.	Min.	Мах.	Target Timeline (%)
	Priority	6	0	N/A	N/A	N/A	N/A
	Standard	9	5	1.98	1	3.5	100%
Q1	Priority Complex	9	0	N/A	N/A	N/A	N/A
2023	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
2025	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
2025	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%
	Priority Complex	9	0	N/A	N/A	N/A	N/A
2023	Complex	12	30	22	11	35.6	3%
YTD Total	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.

	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

2023 Drug Review Decisions Summary

	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

2023 Patient and Caregiver Input Summary

Dri	Patient	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	1 0	0	groups) 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