

From: Scobrick, Timothy HLTH:EX
 To: Lueb, Eric HLTH:EX; Fastagis, Tijana HLTH:EX; Chong, Elaine HLTH:EX
 Subject: RE: DM REQUEST for info
 Date: Monday, September 25, 2017 11:13:23 AM

Of 2016 and 2017 drugs completed (decision made), 51 went to CDR/CDEC. 25/51 went to DBC.

Here is a list that shows the breakdown. Rows in WHITE show CDR-DBC-Ministry alignment. Green = positive listing; Red = Not to list or non-benefit. I will remove some columns from the PPT.

Generic Name	Brand (Trade) Name	Indication	Manufacturer/ Applicant	CDEC R&R	DBC R&R	pCPA (Pan Can)	PharmaCare Status	Decision Date
macitentan	Opsumit	Pulmonary arterial hypertension	Actelion Pharmaceuticals Canada Inc.	List with Criteria & Conditions	List with Criteria	Yes-BC Included	Non-Benefit	26-Jan-16
infliximab SEB	Inflectra	Ankylosing spondylitis, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis	Hospira Healthcare Corporation	List with Conditions	List	Yes-BC Included	Limited Coverage-Special Authority required	19-Feb-16
apixaban	Eliquis	Thromboembolic events (venous), treatment and prevention of recurrence	Bristol-Myers Squibb & Pfizer	List with Conditions	List with Criteria & Conditions	Yes-BC Included	Limited Coverage-Special Authority required	05-Apr-16
eculizumab	Soliris	Atypical Hemolytic Uremic Syndrome	Alexion	Do Not List	Do Not List	Yes-BC Included	Non-Benefit	31-May-16
golimumab	Simponi I.V.	Rheumatoid Arthritis	Janssen	List with Conditions	Do Not List	Yes-BC Included	Non-Benefit	31-May-16
golimumab	Simponi	Ulcerative colitis	Janssen	DNLASP	Do Not List	Yes-BC Included	Non-Benefit	31-May-16
fesoterodine fumarate	Toviaz	Overactive Bladder	Pfizer	List with Criteria	List	N/A	Non-Benefit	04-Aug-16
mirabegron	Myrbetriq	Overactive Bladder	Astellas	List with Criteria & Conditions	List	Yes-BC Opt out	Non-Benefit	04-Aug-16
ivermectin	Rosiver	Rosacea	Galderma	List with Criteria	List with Criteria	Yes-BC Included	Non-Benefit	27-Sep-16
omalizumab	Xolair	Chronic idiopathic urticarial (CIU)	Novartis	Reimburse with clinical criteria and/or conditions	List with Criteria & Conditions	Yes-BC Opt out	Non-Benefit	29-Nov-16
canakinumab	Ilaris	active systemic Juvenile Idiopathic Arthritis (sJIA) in patients 2 years and older	Novartis	Reimburse with clinical criteria and/or conditions	Do Not List	No	Non-Benefit	10-Jan-17
denosumab	Xgeva	Prevention of skeletal-related events due to bone metastases from solid tumours	Amgen Canada Inc	List with clinical criteria and/or conditions (FINAL)	Do Not List	No	Palliative Care Benefit	17-Jan-17
denosumab	Xgeva	Prevention of skeletal-related events due to bone metastases from breast cancer	Amgen Canada Inc	List with clinical criteria and/or conditions (FINAL)	Do Not List	No	Palliative Care Benefit	17-Jan-17
filgrastim	Grastofil Biosimilar (SEB)	Prevention or treatment of neutropenia in various indications	Apotex Inc.	List with Criteria & Conditions	List with Criteria	Yes-BC Lead	Limited Coverage	31-Jan-17
tofacitinib	Xeljanz	Rheumatoid Arthritis	Pfizer Canada Inc.	List with Criteria	List with Criteria & Conditions	Yes-BC Included	Limited Coverage	31-Jan-17
denosumab	Prolia	Postmenopausal osteoporosis	Amgen Canada Inc.	Reimburse with clinical criteria and/or conditions	Do Not List	Yes-BC Opt out	Limited Coverage	14-Feb-17
denosumab	Prolia	Osteoporosis (men)	Amgen Canada Inc.	List with Criteria	Do Not List	Yes-BC Opt out	Limited Coverage	14-Feb-17
lumacaftor-ivacaftor	Orkambi	Cystic Fibrosis, F508del CFTR mutation	Vertex	Do not reimburse	Do Not List	No	Non-Benefit	21-Mar-17
adalimumab	Humira	Hidradenitis Suppurativa	AbbVie Corporation	Reimburse with clinical criteria and/or conditions	Do Not List	Yes-BC Included	Non-Benefit	18-Apr-17
vedolizumab	Entyvio	Ulcerative Colitis	Takeda Canada Inc.	List with Criteria	DNLASP	Yes-BC Included	Limited Coverage	02-May-17
riociguat	Adempas	Pulmonary Arterial Hypertension (WHO group 1)	Bayer Inc.	List with Criteria & Conditions	Do Not List	No	Non-Benefit	02-May-17
mifepristone and misoprostol	Mifegymiso	Medical termination of pregnancy (abortion)	Celopharma Inc.	Reimburse	List	No	Regular Benefit	11-Jul-17
etanercept	Brenzys Biosimilar	Rheumatoid arthritis, ankylosing spondylitis	Merck Canada Inc.	Reimburse with clinical criteria	List	Yes-BC Lead	Limited Coverage	18-Jul-17

				and/or conditions				
teduglutide	Revestive	Short Bowel Syndrome (SBS)	Shire/NPS	Reimburse with clinical criteria and/or conditions	Do Not List	Yes-BC Opt out	Non-Benefit	15-Aug-17
ticagrelor	Brilinta	Prevention of atherothrombotic events with history of myocardial infarction	AstraZeneca	Reimburse with clinical criteria and/or conditions	Do Not List	Yes-BC Opt out	Non-Benefit	05-Sep-17

-----Original Message-----

From: Lun, Eric HLTH:EX
Sent: September-25-17 09:55 AM
To: Scolnick, Timothy HLTH:EX; Fazlagic, Tijana HLTH:EX; Chong, Elaine HLTH:EX
Subject: Re: DM REQUEST for info

The draft slides are doe by Tijana but just need to find the most current draft

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization Pharmaceutical Services Division BC Ministry of Health
Original Message
From: Scolnick, Timothy HLTH:EX
Sent: Monday, September 25, 2017 09:37
To: Fazlagic, Tijana HLTH:EX; Chong, Elaine HLTH:EX
Cc: Lun, Eric HLTH:EX
Subject: FW: DM REQUEST for info

Tijana/Elaine, is #2 assigned to one of you? It's not clear.

-----Original Message-----

From: Lun, Eric HLTH:EX
Sent: Monday, September 25, 2017 9:27 AM
To: Scolnick, Timothy HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Chong, Elaine HLTH:EX; Maglanque, Joyce HLTH:EX
Subject: Re: DM REQUEST for info

Mitch needs the information by noon for a meeting with the DM at 1pm.

Elaine and Tim. Pls begin to compile info:

1. Draft hmm CBN on edrd - Elaine
2. Draft slides on priority drugs that are part of the backlog -
3. Slides of drugs listed and do not list drugs and note which drugs with DNL were also CDR and DBC do not lists - Tim
4. Draft note to address the specific info requests from DM and link back to the material we are providing - Eric and Elaine

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization Pharmaceutical Services Division BC Ministry of Health
Original Message
From: Scolnick, Timothy HLTH:EX
Sent: Sunday, September 24, 2017 22:59
To: Lun, Eric HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Chong, Elaine HLTH:EX; Maglanque, Joyce HLTH:EX
Subject: Re: DM REQUEST for info

OK I will be ready to answer questions if need be.

Timothy Scolnick
Drug Review Process Manager, Formulary Management Drug Intelligence and Optimization BC Ministry of Health
(p) 250-952-1800 | (c) 250-580-7150
timothy.scolnick@gov.bc.ca

> Le 24 sept. 2017 à 21:30, Lun, Eric HLTH:EX <Eric.Lun@gov.bc.ca> a écrit :

>

> Thanks Tijana

>

> Eric Lun, PharmD

> Executive Director, Drug Intelligence & Optimization Pharmaceutical

> Services Division BC Ministry of Health Original Message

> From: Fazlagic, Tijana HLTH:EX

> Sent: Sunday, September 24, 2017 21:00

> To: Lun, Eric HLTH:EX

> Cc: Chong, Elaine HLTH:EX; Scolnick, Timothy HLTH:EX; Maglanque, Joyce

> HLTH:EX

> Subject: Re: DM REQUEST for info

>

>

> Hi,

> I don't think there has been a single CDR do not list recommendation that we have listed. There are a few examples of CDR rec to list with criteria/conditions that we have not listed. Ticagrelor is the most recent example and some in the works. Tim prepared a list of CDR recommendations DBC rec and our decisions for the last DBC so we can use that list. I cAn fill in the story for each on Tuesday.

> Tijana

> Sent from my iPhone

>

>> On Sep 24, 2017, at 8:16 PM, Lun, Eric HLTH:EX <Eric.Lun@gov.bc.ca> wrote:

>>

>> Hi Tim. As **s.22**, may need your help with this request. Pls stand by in the am. Want to ensure that our list AND do not list slides are current.

>>

>> Thanks,

>>

>> Eric Lun, PharmD

>> Executive Director, Drug Intelligence & Optimization Pharmaceutical

>> Services Division BC Ministry of Health Original Message

>> From: Lun, Eric HLTH:EX

>> Sent: Sunday, September 24, 2017 19:24

>> To: Chong, Elaine HLTH:EX; Fazlagic, Tijana HLTH:EX

>> Cc: Maglanque, Joyce HLTH:EX

>> Subject: Fw: DM REQUEST for info

>>

>> Let's discuss this request first thing in the morning so we can gather. We should also take the opportunity to highlight the priority drugs files with positive LOI's.

>>

>> Eric Lun, PharmD

>> Executive Director, Drug Intelligence & Optimization Pharmaceutical

>> Services Division BC Ministry of Health Original Message

>> From: Moneo, Mitch HLTH:EX <Mitch.Moneo@gov.bc.ca>

>> Sent: Sunday, September 24, 2017 14:43

>> To: Lun, Eric HLTH:EX

>> Subject: DM REQUEST for info

>>

>>

>> Hi Eric,

>>

>> The DM got a hold of me today. It appears that the Minister may be looking for a **s.13** will learn more tomorrow morning about timing but we should prepare.

>>

>>

>> One question Steve has asked me to respond to by tomorrow morning. Has there been recent instances of BC and or other jurisdictions listing drugs that get CDR no recommendations? If so what is the context around those listings? Also how often do we not list CDR positive recommendations and why?

>>

>> This may be an opportunity to speak to the products with LOIs that have not been listed due to budget. How many products now and what is the budget?

>>

s.13

>>

>> Thanks

>>

>> Mitch Moneo

>> Pharmaceutical Services Division

>> 250 952-1464

FACT SHEET

Expensive Drugs for Rare Diseases

ISSUE

Expensive Drugs for Rare Diseases (EDRD) present a host of complex challenges, as these drugs are prohibitively expensive, often have limited clinical evidence to support their use, and benefit only a small number of patients. The Ministry of Health is co-leading a P/T Working Group on EDRDs.

KEY FACTS

- EDRD, as currently defined by the Ministry, are drugs used to treat very rare diseases (eg. incidence rate of <1.65 per 100,000) and with an extremely high annual cost (eg. > \$100,000 or more per adult patient).
- The *Canada Health Act* does not include coverage of drugs. Drug coverage including EDRD drugs may vary among provinces and definitions of “rarity” differ among countries.
- Because of the rarity of the diseases, drugs being developed often do not have strong clinical evidence supporting their efficacy and/or safety. Study limitations may include few patients or short term follow-up. Most EDRDs have only demonstrated to slow the certain non-clinical endpoints (e.g. lab test or physical performance result) rather than an increase in survival or cure.
- Companies developing such drugs usually price the product very high, arguing they need to recoup development costs from a small market but do not provide any transparency to justify such prices. The products are typically priced far beyond any individual’s or family’s ability to pay.
- With such considerations of disease rarity, limited evidence, and high per-patient costs, EDRD raise many ethical, clinical and financial issues for provincial payers. Because of the poor evidence and cost challenges, these drugs are generally considered non-benefits. However, the Ministry may consider exceptional last-resort funding requests for certain drugs on a case-by-case basis.
- To review exceptional last-resort requests, the Ministry utilizes a review process which includes advice from an arm’s length independent Advisory Committee and several Clinical Subcommittees. The Ministry also has established a two year BC residency requirement.
- The Advisory Committee includes expert clinicians who treat rare diseases in pediatrics and adults, a critical care medicine specialist, a health economics specialist, an ethics specialist, and representatives from health authority pharmacy and health authority administration. The Advisory Committee is responsible for evaluating patient-specific funding requests and forwards their recommendations to the Ministry for a funding decision. The Advisory Committee’s evaluation may include, but is not limited to: natural disease history, clinical evidence, effectiveness/efficacy of the drug, alternative treatment options, specifics of individual case, expected treatment outcome, consequences if drug is withdrawn/not provided, pharmacoeconomic evidence, budget impact, clinical guidelines, and ethical considerations.
- As of April 2016, case review/funding logistics transferred to Provincial Health Services Authority.
- The Ministry retains a governance role. As of September 2016, the Ministry provides funding for the following 14 EDRDs on an exceptional, last-resort, case-by-case basis:¹ agalsidase alpha (Replagal[®] AF) and agalsidase beta (Fabrazyme) for Fabry Disease; alglucosidase alpha (Myozyme[®]) for Pompe Disease; canakinumab (Ilaris[®]) for Cryopyrin-Associated Periodic Syndromes (CAPS); eculizumab (Soliris[®]) for paroxysmal nocturnal hemoglobinuria (PNH); galsulfase (Naglazyme[®]) for Mucopolysaccharidosis VI (MPS VI); idursulfase (Elaprase[®]) for Mucopolysaccharidosis II (MPS II, Hunter’s Syndrome); imiglucerase (Cerezyme[®]) for Gaucher Disease; ivacaftor (Kalydeco[®]) for cystic fibrosis (CF) G551D mutation; laronidase (Aldurazyme[®]) for Mucopolysaccharidosis I (MPS I); miglustat (Zavesca[®]) for Gaucher Disease and Neimann Pick Type C; nitisinone (Orfadin[®]) for

¹ EDRD Case Tracking Document”. Medical Beneficiary and Pharmaceutical Services Division, Ministry of Health.

FACT SHEET

tyrosinemia type 1; pegademase bovine (Adagen®) for adenosine deaminase (ADA) deficiency; and velaglucerase (VPRIV®) for Gaucher Disease.

Status Update on Specific EDRDs with Recent Decisions or Under Review by the Ministry

- **Soliris®**: In 2014, the Ministry decided not to fund eculizumab for atypical hemolytic uremic syndrome due to unclear clinical benefit and high drug costs. In May 2015, the Canadian Drug Expert Committee (CDEC) provided comments on proposed criteria but did not change the original recommendation in their "Request for Advice". In 2015, the pan-Canadian Pharmaceutical Alliance (pCPA) started negotiations with the manufacturer. These negotiations were not successful and the Ministry upheld its do not fund decision in 2016. In 2015, the Patented Medicine Prices Review Board (PMPRB) launched an allegation that eculizumab is excessively priced. In September 2017, the PMPRB determined that the price of eculizumab was excessive and ordered the manufacturer to pay the Government of Canada a penalty, and reduce the price.
- **Strensiq®**: Asfotase alfa (Strensiq®) is a treatment for pediatric-onset hypophosphatasia. In March 2016, CDEC recommended list with criteria. *Status: pCPA negotiations closed in February 2017 (due to non-agreement of terms). However, negotiations may be re-opened on mutual agreement.*
- **Vimizim®**: CDR recommended to not fund this drug for Mucopolysaccharidosis IVA (Morquio A Syndrome) due to poor clinical evidence. In 2015, the pCPA decided not to negotiate with the manufacturer and the Ministry decided not to fund. CDEC reviewed a resubmission in May 2016 and recommended list with criteria. *Status: pCPA negotiations.*
- **Naglazyme®**: Galsulfase (Naglazyme®) for Mucopolysaccharidosis VI (MPS 6) received a CDEC list with criteria recommendation. *Status: pCPA negotiations.*
- **Kalydeco®**: Ivacaftor (Kalydeco®) is funded for CF patients with the G551D mutation. Two other indications received CDEC list with criteria recommendations. *Status: pCPA negotiations.*
Orkambi®: In October 2016, CDEC issued a do not list recommendation for ivacaftor/lumacaftor (Orkambi®) to treat CF patients with F508del CFTR mutation due to poor clinical evidence. *Status: In March 2017 pCPA decided not to negotiate, and the Ministry decided not to fund.*

P/T and F/P/T Activities

- In April 2013, Health Canada began a consultation regarding a new Orphan Drug Regulation, intended to improve market access to drugs for rare diseases. The Ministry reviewed the draft and provided feedback to Health Canada in January 2014. In May, 2017 Health Canada advised that they are working on a new regulatory roadmap for orphan drugs in lieu of the previously-proposed regulation. The regulatory roadmap will be part of the new Health Canada transformation initiative for all drugs (not necessarily specific to orphan drugs).
- In 2014, the Health Ministers established the P/T EDRD Working Group to explore the management of rare disease drug therapies with evidence-based approaches. BC, Alberta, and Ontario are the co-leads for this working group. In January 2016, a workplan was approved by the Health Ministers in an effort to improve the management of EDRDs. Since then, there has been some progress but EDRDs remain a challenging ongoing matter.

FINANCIAL IMPLICATIONS

- The total drug costs for EDRD in 2016/17 were \$19.5 million and \$17.8 million for 2015/16.²
- Based on list prices, the annual treatment cost for EDRD drugs per patient may range from \$100,000 to over \$3 million, depending on the drug, weight of the patient and dosage regimen.

Approved by:

Ida Stephenson, obo Manjit Sidhu, Finance and Corporate Services Division; May 24, 2017
Mitch Moneo, Pharmaceutical Services Division; September 28, 2017

² EDRD Forecast". Medical Beneficiary and Pharmaceutical Services Division, Ministry of Health.

CDR Submissions completed **348**
 CDR "Do Not List" Recommendations: **130** (~37% of CDR recommendations)

Ministry Coverage Status of the CDR "Do Not List" Recommendations:

NON-BENEFIT		BENEFITS	
n=103		n=7	
adefovir dipivoxil(Hepsera) - NonB until 2008 CDR LWCC alefacept(Amevive) alendronate sodium-cholecalciferol(Fosavance) aliskiren(Rasilez) alogliptin plus metformin(Kazano) alogliptin(Nesina) apremilast(Otezla) aripiprazole(Abilify) asenapine(Saphris) atomoxetine (Strattera) - NonB until 2017 ADHD TR (now generic) azelastine HCl and fluticasone propionate(Dymista) Azilsartan medoxomil + chlorthalidone(Edarbyclor) belimumab(Benlysta) budesonide(Cortiment) buprenorphine transdermal patch (BuTrans) butoconazole nitrate(Gynazole.1) calcitriol(Silkis) ciclesonide nasal spray(Omnaris) cinacalcet hydrochloride(Sensipar) ciprofloxacin hydrochloride / dexamethasone(Ciprodex) cyclosporine(Restasis) dabigatran etexilate(Pradaxa (previously Pradax)) - Orthop daptomycin(Cubicin) darifenacin hydrobromide(Enablex) delta-9-tetrahydrocannabinol / cannabidiol(Sativex) delta-9-tetrahydrocannabinol-cannabidiol(Sativex) desvenlafaxine succinate(Pristiq) dexamethasone intravitreal implant(Ozurdex) doxycycline monohydrate (Aprillon) duloxetine hydrochloride(Cymbalta) - now generic Eculizumab (Soliris) - aHUS RfA; pCPA stopped eculizumab(Soliris) - aHUS eletriptan hydrobromide(Relpax) elosulfase alfa(Vimimizim) - new CDR LWCC; pCPA ongoing eltrombopag (supplied as eltrombopag olamine)(Revolade) eplerenone(Inspra) escitalopram oxalate(Ciprallex) everolimus(AFINITOR) fampridine(Fampyra) fentanyl(Fentora) glatiramer acetate(Copaxone) for CIS Guanfacine hydrochloride(Intuniv XR) infliximab(Remicade) for UC; CDR supported biosimilar 2017 ingenol mebutate(Picato) insulin detemir(Levemir) - NonB 2006-2011 (CDR DNLASP) insulin glargine(Lantus) NonB 2005-2007 interferon beta-1a(Rebif)		levodopa-carbidopa(Duodopa) - NB 2009 to Feb 2017 (now n=4) linacotide(Constella) lisdexafetamine dimesylate(Vyvanse) lomitapide(Luxtapid) loteprednol etabonate(Lotemax) lumacaftor-ivacaftor(Orkambi); pCPA did not negotiate lurasidone(Latuda) memantine hydrochloride(Ebixa) methylaltraxone bromide(Relistor) mixed amphetamine (Adderall XR) - NonB until 2017 ADHD TR; now generic natalizumab(Tysabri) - NonB 2008-2010 (CDR LWCC 2011) norgestimate / ethinyl estradiol(EVRA) omalizumab(Xolair) - 2005 asthma; 2014 urticaria LWCC; 2015 asthma LWCC OnabotulinumtoxinA(Botox) - migraine oxybutynin chloride gel(Gelnique) oxycodone / naloxone(Targin) palonosetron hydrochloride(Aloxi (capsule)) pasireotide(Signifor) penciclovir(Denavir) phleum pratense(Grastek) pirfenidone(Esbriet) - new CDR List with criteria; pcpa done posaconazole(Posanol (formerly Spriafil)) pregabalin(Lyrica) - now generic prucalopride(Resotran) quinagolide(Norprolac) rasagiline mesylate(Azilect) rivastigmine patch (Exelon) ADTI 2016 roflumilast(Daxas) romiplostim(Nplate) rotigotine(Neupro) sapropterin dihydrochloride(Kuvan) - new CDR List with criteria; pCPA ongoing silodosin(Rapaflo) sitagliptin phosphate(Januvia) - previously Pcare benefit (delist) sitaxsentan sodium(Theelin) sodium oxybate(Xyrem) solifenacin succinate(Vesicare) tapentadol(Nucynta CR) telbivudine(Sebivo) teriparatide (rDNA origin)(Forteo) teriparatide(Forteo) tesamorelin(Egrifta) tolvaptan(Samsca) tramadol hydrochloride(Ralivia) tramadol hydrochloride(Tridural) tramadol / acetaminophen(Tramacet) - now generic treprostinil sodium(Remodulin) treprostinil(Remodulin) zoledronic acid(Aclasta) Zolpidem tartrate(Sublinox)	
Legend for Non-Benefit HIGH EXTERNAL DEMANDS but no requests approved PROVIDE SOME EXCEPTIONAL COVERAGE - *Still need to confirm other COVERAGE STATUS CHANGED SINCE		Regular paliperidone(Invega) 2009 - ?PLA Partial NovoMix 30 - cost neutral 2007 Limited Coverage (through Special Authority) certolizumab (Cimzia) for RA - cost savings thru PLA dronedarone (Multaq) - DBC recom. List w/criteria 2011 insulin glargine(Lantus) - PLA 2007 w/restrictive criteria mometasone / formoterol (Zenhale CR) 2011; CDR List w/ Criteria 2012 prasugrel (Effient) 2011 w/ restrictive criteria; CDR Do not list at price 2012	
		NON-BENEFIT EXCEPTIONAL THROUGH EDRD w/PHSA N=5 agalsidase alfa(Replagal) - EDRD/National CFDI 2006 (n=14) agalsidase beta(Fabrazyme) - EDRD/National CFDI 2006 (n=6) idursulfase(Elaprase) - EDRD 2006 (n=1) laronidase(Aldurazyme)-EDRD 2010 (n=2) miglustat(Zavesca) - EDRD 2008 (n=2) (EDRD includes other drugs that were CDR List with Criteria/Conditions like Kalydeco)	
		OTHER N=15 Not PharmaCare - eg. BCCA, CFE HIV/AIDS, renal (9) Manufacturer withdrew (3) No decision needed - information only (3)	

Barry, Brittany JR HLTH:EX

From: Anderson, Kristy GCPE:EX
Sent: Friday, December 8, 2017 3:10 PM
To: Forbes, Brooke GCPE:EX; Fazlagic, Tijana HLTH:EX; Lun, Eric HLTH:EX
Cc: Heinze, Laura R GCPE:EX
Subject: RE: Media Request: Ilrais/Canakinumab

Hi all

MO would like to take this in a bit of another/more succinct direction. Is the ok below?

Arthritis is a complicated disease with many faces, with over 100 types, including juvenile idiopathic arthritis. It is important that anyone with arthritis is able to access the treatment they need and treatments that help them maintain their quality of life. The Ministry of Health will be reaching out to s.22 to looking into this case.

Kristy Anderson
Director, Communications
Ministry of Health
250-952-3387 (office) 778-678-5200 (mobile)
Kristy.Anderson@gov.bc.ca

From: Forbes, Brooke GCPE:EX
Sent: Friday, December 8, 2017 2:53 PM
To: Fazlagic, Tijana HLTH:EX; Lun, Eric HLTH:EX
Cc: Heinze, Laura R GCPE:EX; Anderson, Kristy GCPE:EX
Subject: RE: Media Request: Ilrais/Canakinumab

Thanks Tijana – yes, any more info next week would be great.

Thanks,
Brooke

From: Fazlagic, Tijana HLTH:EX
Sent: Friday, December 8, 2017 2:48 PM
To: Forbes, Brooke GCPE:EX; Lun, Eric HLTH:EX
Cc: Heinze, Laura R GCPE:EX; Anderson, Kristy GCPE:EX
Subject: RE: Media Request: Ilrais/Canakinumab

Hi Brooke,
I am in agreement with this response. I don't know if anyone else covers it, but we need more time to find out. Do you want that information for next week?

From: Forbes, Brooke GCPE:EX
Sent: Friday, December 8, 2017 2:46 PM
To: Fazlagic, Tijana HLTH:EX; Lun, Eric HLTH:EX
Cc: Heinze, Laura R GCPE:EX; Anderson, Kristy GCPE:EX
Subject: Media Request: Ilrais/Canakinumab
Importance: High

Hi Tijana and Eric,

We have a media request on Canakinumab/Ilrais for juvenile idiopathic arthritis. s.22 is advocating for coverage for s.22

Could you please review the recommended response? Do any other jurisdictions list it??

Arthritis is a complicated disease with many faces, with over 100 types, including juvenile idiopathic arthritis. It is important that anyone with arthritis is able to access the treatment they need and treatments that help them maintain their quality of life. But the decisions to fund them with public health care dollars need to be based on clinical evidence.

Canakinumab, commonly known as Ilrais, is a drug that treats juvenile idiopathic arthritis. Ilrais received a Common Drug Review (CDR) recommendation to be reimbursed on the condition that it was no more expensive than the available first-line treatment, tocilizumab, as there was insufficient evidence to determine if it would still be an effective treatment. The cost of a single vial of Ilrais is \$16,000, with annual costs ranging from \$206,000 to \$418,000 per patient. Tocilizumab annual costs range between \$9,000 and \$28,000 per patient. In addition to the CDR recommendation, B.C.'s Drug Benefit Council recommended not to list Ilrais due to a lack of evidence and high product cost.

Thanks,
Brooke

Brooke Forbes
Public Affairs Officer | Ministry of Health
Government Communications and Public Engagement
250-952-1688 | 778-678-5879 | brooke.forbes@gov.bc.ca

Barry, Brittany JR HLTH:EX

From: Lee, Diane HLTH:EX
Sent: Friday, December 8, 2017 3:53 PM
To: Fazlagic, Tijana HLTH:EX
Subject: RE: Provincial survey for Canakinumab/Iltrais for juvenile idiopathic arthritis

Hi Tijana,

I sent out the survey to the jurisdictions and I'll provide you with their responses as soon as I have most of them.

Thanks,
Diane

From: Lee, Diane HLTH:EX
Sent: Friday, December 8, 2017 3:25 PM
To: Fazlagic, Tijana HLTH:EX
Subject: RE: Provincial survey for Canakinumab/Iltrais for juvenile idiopathic arthritis

Hi Tijana,

I will do that right away.

To clarify, do you want to know if other jurisdictions are covering Canakinumab/Iltrais for juvenile idiopathic arthritis?

Is there anything else that I should ask the jurisdictions?

Diane

From: Fazlagic, Tijana HLTH:EX
Sent: Friday, December 8, 2017 2:59 PM
To: Lee, Diane HLTH:EX
Subject: Provincial survey for Canakinumab/Iltrais for juvenile idiopathic arthritis

Hi Diane,

We got a media request for Canakinumab/Iltrais for juvenile idiopathic arthritis. Please send out a provincial survey either today or first thing Monday morning. I told GCPE that we won't have answer for them until next week.

Thank you
Tijana

Tijana Fazlagic PharmD, BSP, MSc.
Director, Formulary Management
Pharmaceutical Services Division
604 374-2609
tijana.fazlagic@gov.bc.ca

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Barry, Brittany JR HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Sunday, December 10, 2017 9:09 PM
To: Chong, Elaine HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Bouma, Susan HLTH:EX
Subject: Re: in relation to the case from friday

Thank. Elaine

Tijana and Sue. For the three questions below, can FM follow up with the first and can SA follow up with the other two please?

Thanks

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization
Pharmaceutical Services Division
BC Ministry of Health

From: Chong, Elaine HLTH:EX
Sent: Sunday, December 10, 2017 20:57
To: Lun, Eric HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Bouma, Susan HLTH:EX
Subject: Re: in relation to the case from friday

I think the PLA is specific to our s.22 and also specific to CAPS which has unique dosing that can be capped at s.17 monograph dosing. I can check with BMSRS on Mon.

EC

On Dec 10, 2017, at 8:36 PM, Lun, Eric HLTH:EX <Eric.Lun@gov.bc.ca> wrote:

Thanks. Do you recall whether the PLA is specific to CAPS or can the pricing be used for other indications.

Sue - will prob need some support from SA and possibly RAaDBAC on this. In the mean time, can you advise how any previous requests for sJIA was handled before?

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization
Pharmaceutical Services Division
BC Ministry of Health

From: Chong, Elaine HLTH:EX
Sent: Sunday, December 10, 2017 20:21
To: Lun, Eric HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX
Subject: Re: in relation to the case from friday

Eric,

Yes we fund s.22

for canakinumab - it is for the CAPS indication though, not SJIA.

EC

On Dec 10, 2017, at 8:06 PM, Lun, Eric HLTH:EX <Eric.Lun@gov.bc.ca> wrote:

For follow up on Monday. I think we cover one pt thru edrd process right Elaine?

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization
Pharmaceutical Services Division
BC Ministry of Health

From: Anderson, Kristy GCPE:EX <Kristy.Anderson@gov.bc.ca>
Sent: Sunday, December 10, 2017 19:29
To: Lun, Eric HLTH:EX; Forbes, Brooke GCPE:EX; Will, Jordan HLTH:EX
Subject: FW: in relation to the case from friday

Hi all – just spoke with the MO who is looking for the below by Tuesday at the latest.
Really they want to know:

- Who else (PTs) may cover it and through which programs (formulary or ...)
- What other treatments are available – including off label (which is how I think biologics may be applicable in this case)
- What other treatments s.22 may have tried – consent was provided from
Kassandra from s.22 on Friday to look into the case – Jordan can you
advise if MOH has reached out at this point/if you received that consent.

Thanks,

Kristy Anderson

Director, Communications

Ministry of Health

250-952-3387 (office) 778-678-5200 (mobile)

Kristy.Anderson@gov.bc.ca

From: Singh, Jasmyn HLTH:EX
Sent: Sunday, December 10, 2017 6:09 PM
To: Anderson, Kristy GCPE:EX
Cc: Lun, Eric HLTH:EX
Subject: in relation to the case from friday
Importance: High

Eric, I am including you in this email as I presuming you were given a heads up about the Premiers office receiving a letter from a constituent s.22 re: coverage of canakinumab (Ilaris®) s.22 that spurred requests for media comment

s.22

-I will need an update tomorrow / Tuesday re: this case, In addition, need to know what other provinces provide it under their formulary, I know that the decision was made in Jan of this year to declare it a non benefit

From the DBC report – potential other options

"For the treatment of active sJIA in patients two years of age and older who, due to intolerance or lack of efficacy, have not adequately responded to: non-steroidal anti-canakinumab (Ilaris®) 3452

inflammatory drugs (NSAIDs) AND systemic corticosteroid drugs (with or without methotrexate).

- Adalimumab (Humira), abatacept (Orencia), etanercept (Enbrel) and infliximab (Remicade)

are all biologics which are not indicated for sJIA but can potentially be used for treatment of

sJIA. They are all Limited Coverage benefits for indications other than sJIA and have pediatric rheumatologist exemptions.

- The comparator drug, kineret (Anakinra) indicated for sJIA; however, as noted by the clinical expert in the Common Drug Review (CDR) report, it is often prescribed to patients with sJIA. It is not an eligible PharmaCare benefit. In British Columbia, kineret (Anakinra) is provided to patients with sJIA on an exceptional case-by-case scenario."

Barry, Brittany JR HLTH:EX

From: Lee, Diane HLTH:EX
Sent: Monday, December 11, 2017 10:01 AM
To: Fazlagic, Tijana HLTH:EX
Subject: Jurisdictional survey: canakinumab (Ilaris) for JIA

s.13,s.16

The responses that I've received so far.

Diane Lee, BSc (Pharm), RPh
Pharmacist
Formulary Management | Drug Intelligence and Optimization
Pharmaceutical Services Division | BC Ministry of Health
303-960 Quayside Drive, New Westminster, BC. V3M 6G2
t 604-660-1280 | f 604-660-2108
e Diane.Lee@gov.bc.ca

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Barry, Brittany JR HLTH:EX

From: Bouma, Susan HLTH:EX
Sent: Monday, December 11, 2017 10:07 AM
To: Chong, Elaine HLTH:EX
Cc: Lun, Eric HLTH:EX; Fazlagic, Tijana HLTH:EX
Subject: Re: in relation to the case from friday

We are on it!

Sue

Sent from my iPhone

On Dec 11, 2017, at 8:16 AM, Chong, Elaine HLTH:EX <Elaine.Chong@gov.bc.ca> wrote:

All,

BMSRS confirmed that the PLA is specific for s.22 only as determined by the Province.

EC

On Dec 10, 2017, at 10:06 PM, Bouma, Susan HLTH:EX <Susan.Bouma@gov.bc.ca> wrote:

Hi

This is s.22 I was asked to call on Friday, which I did. s.22
s.22

Sue

Sent from my iPhone

On Dec 10, 2017, at 8:57 PM, Chong, Elaine HLTH:EX <Elaine.Chong@gov.bc.ca> wrote:

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Sent: Sunday, December 10, 2017 19:29
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(mobile)

Kristy.Anderson@gov.bc.ca

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Cc: Lun, Eric HLTH:EX

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Barry, Brittany JR HLTH:EX

From: Lee, Diane HLTH:EX
Sent: Monday, December 11, 2017 10:31 AM
To: Fazlagic, Tijana HLTH:EX
Subject: FW: Jurisdictional survey: canakinumab (Ilaris) for JIA

Hi Tijana,

Do you want further details from Karen in AB (as described in her email below)?

Thanks,
Diane

From: Karen Smilski [<mailto:karen.smilski@gov.ab.ca>]
Sent: Monday, December 11, 2017 10:28 AM
To: Lee, Diane HLTH:EX
Subject: RE: Jurisdictional survey: canakinumab (Ilaris) for JIA

Hi Diane;

s.13,s.16

Thanks,
K

From: Lee, Diane HLTH:EX [<mailto:Diane.Lee@gov.bc.ca>]
Sent: Monday, December 11, 2017 11:10 AM
To: 'brcairns@gov.pe.ca'; 'Kevin.Pothier@gnb.ca'; 'dherbert@health.gov.sk.ca'; 'abderraouf.salhi@inesss.qc.ca'; 'Karina.Lee@ontario.ca'; XT:HLTH Jardine, Leanne <leanne.jardine@gnb.ca>; 'karen.smilski@gov.ab.ca'; 'Charlene.Maharaj@gov.mb.ca'; 'Kathleen.Coleman@novascotia.ca'; 'sean.eichendorf@gov.yk.ca' <sean.eichendorf@gov.yk.ca>; 'Mullins, Marguerite' <margueritemullins@gov.nl.ca>
Subject: RE: Jurisdictional survey: canakinumab (Ilaris) for JIA

Hello,

My apologies for the second email. Could you please also let me know if your jurisdiction covers canakinumab (Ilaris) for juvenile idiopathic arthritis on an **exceptional (or case-by-case)** basis?

Thank you again,
Diane

From: Lee, Diane HLTH:EX

Sent: Friday, December 8, 2017 3:52 PM

To: 'brcairns@gov.pe.ca'; 'Kevin.Pothier@gnb.ca'; 'dherbert@health.gov.sk.ca'; 'abderraouf.salhi@inesss.qc.ca'; 'Karina.Lee@ontario.ca'; XT:HLTH Jardine, Leanne; 'karen.smilski@gov.ab.ca'; 'Charlene.Maharaj@gov.mb.ca'; 'Kathleen.Coleman@novascotia.ca'; 'sean.eichendorf@gov.yk.ca'; 'Mullins, Marguerite'

Subject: Jurisdictional survey: canakinumab (Ilaris) for JIA

Hi there,

Could you please tell me if your jurisdiction covers canakinumab (Ilaris) for juvenile idiopathic arthritis?

We would appreciate a response as soon as possible.

Thank you!

Diane Lee, BSc (Pharm), RPh

Pharmacist

Formulary Management | Drug Intelligence and Optimization

Pharmaceutical Services Division | BC Ministry of Health

303-960 Quayside Drive, New Westminster, BC. V3M 6G2

t 604-660-1280 | f 604-660-2108

e Diane.Lee@gov.bc.ca

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Barry, Brittany JR HLTH:EX

From: Abderraouf Salhi <abderraouf.salhi@inesss.qc.ca>
Sent: Monday, December 11, 2017 11:10 AM
To: Lee, Diane HLTH:EX
Cc: brcairns@gov.pe.ca; Dorothea.Talsma@gov.yk.ca; Rachel.Chervallath@health.gov.sk.ca; Karina.Lee@ontario.ca; Kathleen.Shipp@gov.ns.ca; Charlene.huntley@gov.mb.ca; margueritemullins@gov.nl.ca; XT:HLTH Jardine, Leanne; karen.smilski@gov.ab.ca; Fazlagic, Tijana HLTH:EX; Giguere, Marie-Helene HLTH:EX
Subject: RE: Jurisdictional survey: canakinumab (Ilaris) for JIA

Hi Diane,

s.13,s.16

Hope it's helpful

Regards

Abderraouf SALHI

Direction du Médicament (DM)

Institut national d'excellence en santé et en services sociaux (INESSS)

2535, boulevard Laurier, 5e étage.

Québec, (Québec) G1V 4M3

Tél. (418) 643-1339

Télé. (418) 646-8349

www.inesss.qc.ca

Please note that this e-mail is a personal translation made by the author and that it has not been revised by an official translator. The Institut national d'excellence en santé et en services sociaux cannot be held responsible for any mistranslation or shift in meaning. Veuillez noter que ce courriel est une traduction personnelle de l'auteur et n'a pas été révisée par un traducteur officiel. L'Institut national d'excellence en santé et en services sociaux ne pourra être tenu responsable pour tout contresens ou glissement de sens.



Avant d'imprimer, pensez à l'environnement

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De : "Lee, Diane HLTH:EX"

A : "brcairns@gov.pe.ca" <brcairns@gov.pe.ca>, "Kevin.Pothier@gnb.ca" <Kevin.Pothier@gnb.ca>, "dherbert@health.gov.sk.ca" <dherbert@health.gov.sk.ca>, "abderraouf.salhi@inesss.qc.ca" <abderraouf.salhi@inesss.qc.ca>, "Karina.Lee@ontario.ca" <Karina.Lee@ontario.ca>, "XT:HLTH Jardine, Leanne", "karen.smilski@gov.ab.ca" <karen.smilski@gov.ab.ca>, "Charlene.Maharaj@gov.mb.ca" <Charlene.Maharaj@gov.mb.ca>, "Kathleen.Coleman@novascotia.ca" <Kathleen.Coleman@novascotia.ca>, "sean.eichendorf@gov.yk.ca", "Mullins, Marguerite"

Date : 2017-12-11 13:17

Objet : RE: Jurisdictional survey: canakinumab (Ilaris) for JIA

Hello,

My apologies for the second email. Could you please also let me know if your jurisdiction covers canakinumab (Ilaris) for juvenile idiopathic arthritis on an **exceptional (or case-by-case)** basis?

Thank you again,
Diane

From: Lee, Diane HLTH:EX

Sent: Friday, December 8, 2017 3:52 PM

To: 'brcairns@gov.pe.ca'; 'Kevin.Pothier@gnb.ca'; 'dherbert@health.gov.sk.ca';
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Subject: Jurisdictional survey: canakinumab (Ilaris) for JIA

Hi there,

Could you please tell me if your jurisdiction covers canakinumab (Ilaris) for juvenile idiopathic arthritis?

We would appreciate a response as soon as possible.

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Diane Lee, BSc (Pharm), RPh

Pharmacist

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Barry, Brittany JR HLTH:EX

From: Lee, Diane HLTH:EX
Sent: Monday, December 11, 2017 12:04 PM
To: Fazlagic, Tijana HLTH:EX
Subject: FW: Jurisdictional survey: canakinumab (Ilaris) for JIA

s.13,s.16

Diane

From: Greiss, David (MOHLTC) [<mailto:David.Greiss@ontario.ca>]
Sent: Monday, December 11, 2017 11:43 AM
To: Lee, Diane HLTH:EX
Cc: Lee, Karina (MOHLTC)
Subject: RE: Jurisdictional survey: canakinumab (Ilaris) for JIA

Hello Diane,

s.13,s.16

Best,
David

From: Lee, Diane HLTH:EX [<mailto:Diane.Lee@gov.bc.ca>]
Sent: December-11-17 1:10 PM
To: 'brcairns@gov.pe.ca'; 'Kevin.Pothier@gnb.ca'; 'dherbert@health.gov.sk.ca'; 'abderraouf.salhi@inesss.qc.ca'; 'Karina.Lee@ontario.ca'; XT:HLTH Jardine, Leanne; 'karen.smilski@gov.ab.ca'; 'Charlene.Maharaj@gov.mb.ca'; 'Kathleen.Coleman@novascotia.ca'; 'sean.eichendorf@gov.yk.ca'; 'Mullins, Marguerite'
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Barry, Brittany JR HLTH:EX

From: Lee, Diane HLTH:EX
Sent: Monday, December 11, 2017 12:42 PM
To: Fazlagic, Tijana HLTH:EX
Subject: FW: Jurisdictional survey: canakinumab (Ilaris) for JIA

s.13,s.16

Diane

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Cc: brcairns@gov.pe.ca; Dorothea.Talsma@gov.yk.ca; Rachel.Cheruvallath@health.gov.sk.ca; Karina.Lee@ontario.ca; Kathleen.Shipp@gov.ns.ca; Charlene.huntley@gov.mb.ca; margueritemullins@gov.nl.ca; XT:HLTH Jardine, Leanne; karen.smilski@gov.ab.ca; Fazlagic, Tijana HLTH:EX; Giguere, Marie-Helene HLTH:EX
Subject: RE: Jurisdictional survey: canakinumab (Ilaris) for JIA

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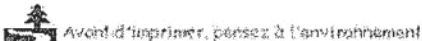
s.13,s.16

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Abderraouf SALHI
Direction du Médicament (DM)
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2535, boulevard Laurier, 5e étage.
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De : "Lee, Diane HLTH:EX" <Diane.Lee@gov.bc.ca>
À : "brcairns@gov.pe.ca" <brcairns@gov.pe.ca>, "Kevin.Pothier@gnb.ca" <Kevin.Pothier@gnb.ca>, "dherbert@health.gov.sk.ca" <dherbert@health.gov.sk.ca>, "abderraouf.salhi@inesss.qc.ca" <abderraouf.salhi@inesss.qc.ca>, "Karina.Lee@ontario.ca" <Karina.Lee@ontario.ca>, "XT:HLTH Jardine, Leanne" <leanne.jardine@gnb.ca>, "karen.smilski@gov.ab.ca" <karen.smilski@gov.ab.ca>, "Charlene.Maharaj@gov.mb.ca" <Charlene.Maharaj@gov.mb.ca>, "Kathleen.Coleman@novascotia.ca" <Kathleen.Coleman@novascotia.ca>, "sean.eichendorf@gov.yk.ca" <sean.eichendorf@gov.yk.ca>, "Mullins, Marguerite" <margueritemullins@gov.nl.ca>
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Barry, Brittany JR HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Monday, December 11, 2017 3:42 PM
To: Fazlagic, Tijana HLTH:EX; Bouma, Susan HLTH:EX; Chong, Elaine HLTH:EX
Subject: Re: in relation to the case from friday

Thanks Tijana. Useful info to include as an appendix in the summary IBN.

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization
Pharmaceutical Services Division
BC Ministry of Health

From: Fazlagic, Tijana HLTH:EX
Sent: Monday, December 11, 2017 14:56
To: Bouma, Susan HLTH:EX; Lun, Eric HLTH:EX; Chong, Elaine HLTH:EX
Subject: RE: in relation to the case from friday

s.13,s.16

From: Fazlagic, Tijana HLTH:EX
Sent: Monday, December 11, 2017 2:49 PM
To: Bouma, Susan HLTH:EX; Lun, Eric HLTH:EX; Chong, Elaine HLTH:EX
Subject: RE: in relation to the case from friday
From the responses we have received so far s.13,s.16
s.13,s.16

Tijana

From: Bouma, Susan HLTH:EX
Sent: Monday, December 11, 2017 1:26 PM
To: Lun, Eric HLTH:EX; Chong, Elaine HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX
Subject: RE: in relation to the case from friday
TRs are done and in your e-Approve Eric
From: Lun, Eric HLTH:EX
Sent: Sunday, December 10, 2017 9:09 PM
To: Chong, Elaine HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Bouma, Susan HLTH:EX
Subject: Re: in relation to the case from friday

Thank, Elaine

Tijana and Sue. For the three questions below, can FM follow up with the first and can SA follow up with the other two please?

Thanks

Eric Lun, PharmD

Executive Director, Drug Intelligence & Optimization

Pharmaceutical Services Division

BC Ministry of Health

From: Chong, Elaine HLTH:EX
Sent: Sunday, December 10, 2017 20:57
To: Lun, Eric HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Bouma, Susan HLTH:EX
Subject: Re: in relation to the case from friday

I think the PLA is specific to our s.22 and also specific to CAPS which has unique dosing that can be capped at s.17 monograph dosing. I can check with BMSRS on Mon.

EC

On Dec 10, 2017, at 8:36 PM, Lun, Eric HLTH:EX <Eric.Lun@gov.bc.ca> wrote:

Thanks. Do you recall whether the PLA is specific to CAPS or can the pricing be used for other indications.

Sue - will prob need some support from SA and possibly RAaDBAC on this. In the mean time, can you advise how any previous requests for sJIA was handled before?

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization
Pharmaceutical Services Division
BC Ministry of Health

From: Chong, Elaine HLTH:EX
Sent: Sunday, December 10, 2017 20:21
To: Lun, Eric HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX
Subject: Re: in relation to the case from friday

Eric,
Yes we fund s.22 for canakinumab - it is for the CAPS indication though, not sJIA.
EC

On Dec 10, 2017, at 8:06 PM, Lun, Eric HLTH:EX <Eric.Lun@gov.bc.ca> wrote:

For follow up on Monday. I think we cover s.22 thru edrd process right Elaine?

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization
Pharmaceutical Services Division
BC Ministry of Health

From: Anderson, Kristy GCPE:EX <Kristy.Anderson@gov.bc.ca>
Sent: Sunday, December 10, 2017 19:29
To: Lun, Eric HLTH:EX; Forbes, Brooke GCPE:EX; Will, Jordan HLTH:EX
Subject: FW: in relation to the case from friday

Hi all – just spoke with the MO who is looking for the below by Tuesday at the latest.
Really they want to know:

- Who else (PTs) may cover it and through which programs (formulary or ...)
- What other treatments are available – including off label (which is how I think biologics may be applicable in this case)
- What other treatments s.22 may have tried – consent was provided from
Kassandra from s.22 on Friday to look into the case – Jordan can you
advise if MOH has reached out at this point/if you received that consent.

Thanks,
Kristy Anderson
Director, Communications
Ministry of Health
250-952-3387 (office) 778-678-5200 (mobile)
Kristy.Anderson@gov.bc.ca

From: Singh, Jasmyn HLTH:EX
Sent: Sunday, December 10, 2017 6:09 PM
To: Anderson, Kristy GCPE:EX
Cc: Lun, Eric HLTH:EX
Subject: in relation to the case from friday
Importance: High

Eric, I am including you in this email as I presuming you were given a heads up about the Premiers office receiving a letter from a constituents.22 re: coverage of canakinumab (Ilaris®) for s.22 that spurred requests for media comment

s.22

-I will need an update tomorrow / Tuesday re: this case, In addition, need to know what other provinces provide it under their formulary, I know that the decision was made in Jan of this year to declare it a non benefit

From the DBC report – potential other options

“For the treatment of active sJIA in patients two years of age and older who, due to intolerance or lack of efficacy, have not adequately responded to: non-steroidal anti-canakinumab (Ilaris®) 3452

inflammatory drugs (NSAIDs) AND systemic corticosteroid drugs (with or without methotrexate).

- Adalimumab (Humira), abatacept (Orencia), etanercept (Enbrel) and infliximab (Remicade)

are all biologics which are not indicated for sJIA but can potentially be used for treatment of

sJIA. They are all Limited Coverage benefits for indications other than sJIA and have pediatric rheumatologist exemptions.

- The comparator drug, kineret (Anakinra) indicated for sJIA; however, as noted by the clinical expert in the Common Drug Review (CDR) report, it is often prescribed to patients with sJIA. It is not an eligible PharmaCare benefit. In British Columbia, kineret (Anakinra) is provided to patients with sJIA on an exceptional case-by-case scenario.”

Barry, Brittany JR HLTH:EX

From: Dix.MLA, Adrian <Adrian.Dix.MLA@leg.bc.ca>
Sent: Tuesday, December 12, 2017 12:35 PM
To: Minister, HLTH HLTH:EX
Subject: 1099666 s.22 incoming -FW: government funding for Canakinumab
Attachments: Letter to government 1.docx

Categories: FYI

HLTH MO to PSD – dd

From: s.22
Sent: Tuesday, December 12, 2017 7:36 AM
To: premier@gov.bc.ca; Dix.MLA, Adrian
Cc: Wilson, Jennifer
Subject: government funding for Canakinumab

Dear Sirs,

Please read the attached letter which stresses the importance for the government to fund the drug Canakinumab.^{s.22}
s.22 and if this drug is covered by Pharmacare more children
can look forward to a pain free life. Please, please give this serious consideration and act quickly. Children are suffering.

Sincerely,

s.22

December 11, 2017

By e-mail: premier@gov.bc.ca
adrian.dix.MLA@leg.bc.ca

The Honourable Premier John Horgan
P.O. Box 9041 Stn Prov Govt
Victoria, BC V8W 9E1

The Honourable Minister Adrian Dix
Room 337 Parliament Buildings
Victoria, BC V8V 1X4

Dear Premier Horgan and Minister Dix:

Re: Coverage of Canakinumab

I write to you to stress the critical importance for drugs like Canakinumab, a highly effective but expensive medicine not currently covered by BC Pharmacare be made available to children who desperately need them.

I am a s.22 who was diagnosed s.22 with Systemic Juvenile Arthritis, a rare form of childhood arthritis. When I heard about s.22 s.22

s.22

s.22 It is crucial to have Canakinumab funded so that others that need it can look forward to a much brighter future.

With Canakinumab being funded by the government s.22 and other children's futures could have a different outcome and the potential to live a life pain free, have a happy childhood, and grow into a healthy adult. Children should not have to wait years to get the disease under control. This drug is available right now! The only thing standing in the way is government's decision on whether to cover this drug.

Please help children become painfree.

Sincerely,
s.22

Barry, Brittany JR HLTH:EX

From: Forbes, Brooke GCPE:EX
Sent: Tuesday, December 12, 2017 1:35 PM
To: Lun, Eric HLTH:EX
Cc: Chong, Elaine HLTH:EX; Fazlagic, Tijana HLTH:EX; Bouma, Susan HLTH:EX; Anderson, Kristy GCPE:EX
Subject: Ilaris IN
Attachments: IN_Ilaris_Dec 12 DRAFT_132pm.docx

Importance: High

Hi Eric,

Here is the draft IN on ilaris.

Thanks,
Brooke

Brooke Forbes
Public Affairs Officer | Ministry of Health
Government Communications and Public Engagement
250-952-1688 | 778-678-5879 | brooke.forbes@gov.bc.ca

ADVICE TO MINISTER

CONFIDENTIAL ISSUES NOTE	Ilaris / Canakinumab
Ministry: Health Date: Dec. 11, 17; Dec. 12, 17 Minister Responsible: Adrian Dix	

ISSUE SUMMARY:

- On December 7, 2017, the ministry was contacted by the media about s.22 who is advocating for coverage of canakinumab, commonly known as ilaris, which treats Systemic Juvenile Idiopathic Arthritis (sJIA).
- s.22 also directly contacted the Premier's office, the Minister's office and the manufacturer, Novartis Pharmaceuticals.
- Health Canada approved the sale of ilaris in December 2013.
- In June 2016, the Common Drug Review (CDR) recommendation was to reimburse ilaris on the condition that there was a substantial price reduction, and that its price would not exceed the first-line treatment, tocilizumab.
- The pan-Canadian Pharmaceutical Alliance (pCPA) entered into negotiations with the manufacturer Novartis Pharmaceuticals, but negotiations were closed as an agreement was not reached.
- In January 2017, B.C.'s Drug Benefit Council recommended not to list ilaris as the drug was not cost effective.
- A petition to publicly fund canakinumab in BC has received over 2,700 as of Dec. 12, 17.

BACKGROUND REGARDING THE ISSUE:

- sJIA causes inflamed, swollen joints which causes pain and stiffness. Its cause is unknown and there is no cure, however it is possible for the disease to go into remission, with some children growing out of it after receiving treatment.
- The following drugs are approved in Canada to treat sJIA:
 - tocilizumab – a monthly infusion in the hospital that takes approximately 1 hour
 - anakinra – a daily subcutaneous injection that can take place in-office or at home with training
 - canakinumab – a monthly subcutaneous injection that can take place in-office or at home with training.
- PharmaCare fully covers tocilizumab under its Special Authority program, and covers anakinra on an exceptional case-by-case basis.
- The cost of ilaris is approximately \$19,000 a vial with an annual cost of \$208,000 to \$416,000 per patient.
- The annual cost of tocilizumab ranges from \$9,402 to \$28,207 per patient.
- The annual cost of anakinra ranges from xxxx to xxxx per patient.
- Do other jurisdictions cover ilaris for sJIA?

Comment [FBG1]: 2016 source says \$16,000:
https://www.cadth.ca/sites/default/files/cdr/complete/SR0463_complete_II_aris_sJIA_june_21_16_e.pdf

Comment [FBG2]: Petition says other jurisdictions fund it – but for which indication?

ADVICE TO MINISTER

- Ilaris also treats another indication, Cryopyrin-Associated Periodic Syndrome (CAPS).
- Ilaris for the treatment of CAPS received a 'do not list' recommendation from the CDR due to a lack of clinical benefit.
s.13,s.16

Comment [FBG3]: Does any other jurisdiction fund Ilaris for CAPS?

Comment [FBG4]: http://www2.gnb.ca/content/gnb/en/news/news_release/2014-07-0939.html

CONFIDENTIAL:

s.13,s.22

s.13,s.22

- The CDR found that Ilaris for the treatment of sIJA had a statistically significant and clinically meaningful benefit in relation to health-related quality of life, pain, and functionality after 29 days of treatment.
- However, the CDR also found since Ilaris was not only tested against placebos and not other treatments, there was insufficient evidence to determine whether it would still be an effective treatment for patients who have previously discontinued treatment with other biologic drugs, including tocilizumab, due to a lack of efficacy or intolerance.
- The CDR stated that the cost per vial of Ilaris would have to be reduced by at least 89% to more than 93% depending on the weight of the patient to have comparable annual costs to tocilizumab.

ADVICE AND RECOMMENDED RESPONSE:

- Arthritis is a complicated disease with many faces, with over 100 types, including juvenile idiopathic arthritis.

s.13,s.22

- We continue to look into the situation and will keep ^{s.22} informed.

If asked about SIJA:

- As someone with a chronic disease, I know how much it can impact everyday life.
- I understand there is a small number of children in BC who live with SIJA, with families who love and support them.
- It is important that anyone with this diagnosis is able to access the treatment they need and treatments that help them maintain their quality of life.
- Tocilizumab is the first-line treatment for this type of juvenile arthritis, and is fully covered under BC's PharmaCare.

ADVICE TO MINISTER

- BC also covers another treatment, anakinra, on an exceptional, case-by-base basis.

Communications Contact: Brooke Forbes Reviewer:

Program Area Contact: Elaine Chong; Eric Lun

File Created: Dec. 11, 17

File Updated: Dec. 12, 17

Minister's Office	Program Area	Deputy	HLTH Communications

Barry, Brittany JR HLTH:EX

From: Chong, Elaine HLTH:EX
Sent: Tuesday, December 12, 2017 3:54 PM
To: Bouma, Susan HLTH:EX; Fazlagic, Tijana HLTH:EX
Cc: Dizon, Kristine D HLTH:EX
Subject: Fwd: 1099621 - Telephone Response Assignment
Attachments: 1099621: PUBLIC CALLER: s.22

ATT00001.htm

Hi Sue and Tijana,

I think one of you is handling canakinumab? Please advise who this should be reassigned to.

Thanks,
EC

Begin forwarded message:

From: "Dizon, Kristine D HLTH:EX" <Kristine.Dizon@gov.bc.ca>
Date: December 12, 2017 at 3:51:11 PM PST
To: "Chong, Elaine HLTH:EX" <Elaine.Chong@gov.bc.ca>
Subject: 1099621 - Telephone Response Assignment

Elaine – telephone response assignment sent to us. See incoming attached. Who to forward to?

Kristine Dizon | Administrative Assistant
Decision Support & Evaluation Guidance
Drug Intelligence & Optimization | Pharmaceutical Services
BC Ministry of Health
Ph: 604-660-5365 Fax: 604-660-2108

WARNING – CONFIDENTIALITY NOTICE

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Barry, Brittany JR HLTH:EX

From: Tyson, Jo HLTH:EX
Sent: Tuesday, December 12, 2017 1:46 PM
To: McClymont, Brenda HLTH:EX
Subject: 1099621: PUBLIC CALLER: s.22

Tell staff to impress that we cannot discuss another person due to privacy concerns.

From: McClymont, Brenda HLTH:EX
Sent: Tuesday, December 12, 2017 1:43 PM
To: Tyson, Jo HLTH:EX
Cc: Stevens, Sandy HLTH:EX
Subject: RE: PUBLIC CALLER: s.22

I sense that will make a long conversation. But if you insist I will assign. I don't think staff will agree though.

From: Tyson, Jo HLTH:EX
Sent: Tuesday, December 12, 2017 1:39 PM
To: McClymont, Brenda HLTH:EX
Subject: RE: PUBLIC CALLER: s.22

I agree, however, can someone just let her know where the ministry stands on that drug?

From: McClymont, Brenda HLTH:EX
Sent: Tuesday, December 12, 2017 1:17 PM
To: HLTH Corporate Operations HLTH:EX; Tyson, Jo HLTH:EX
Cc: Perez De Tagle, Michael HLTH:EX; Stevens, Sandy HLTH:EX; Scott, Pam HLTH:EX
Subject: PUBLIC CALLER: s.22

Jo, I don't feel it is appropriate to call this person to discuss coverage for someone she doesn't know.
Please advise.

thanks

From: HLTH Corporate Operations HLTH:EX
Sent: Tuesday, December 12, 2017 10:59 AM
To: McClymont, Brenda HLTH:EX; Stevens, Sandy HLTH:EX
Cc: Tyson, Jo HLTH:EX; Perez De Tagle, Michael HLTH:EX; HLTH Corporate Operations HLTH:EX
Subject: PUBLIC CALLER: s.22

Hi Brenda/ Sandy,

I received a call from s.22
s.22

in regards of the story was aired on s.22

s.22 would like to know the status of Ministry of Health decision is regarding the approval of this drug fo^{s.22}

Please have someone return^{s.2}₂ call.

Thank you,

Paul Landry
Corporate Operations Unit
Ministry of Health
PO Box 9639
STN PROV GOVT
Victoria BC V8W 9P1

(250) 952-1623

Barry, Brittany JR HLTH:EX

From: Lee, Diane HLTH:EX
Sent: Wednesday, December 13, 2017 10:30 AM
To: Fazlagic, Tijana HLTH:EX
Subject: RE: Updated - canakinumab (Ilaris) JIA jurisdictional survey

I saved the Dec 2017 jurisdictional survey in the LAN: Z:\DIO-FM-Access Restricted\FORMULARY MGMT 70325\Drugs (-30)\canakinumab\canakinumab (Ilaris) 3452 CDR\Information Documents\Canakinumab (Ilaris) JIA jurisdictional survey - December 2017.docx

Note that a jurisdictional scan was also conducted in May 2017.

Thanks,
Diane

From: Fazlagic, Tijana HLTH:EX
Sent: Wednesday, December 13, 2017 9:47 AM
To: Lee, Diane HLTH:EX
Subject: RE: Updated - canakinumab (Ilaris) JIA jurisdictional survey

Excellent, thank you!

From: Lee, Diane HLTH:EX
Sent: Wednesday, December 13, 2017 9:15 AM
To: Fazlagic, Tijana HLTH:EX
Subject: Updated - canakinumab (Ilaris) JIA jurisdictional survey

Hi Tijana,

I received some additional replies from the jurisdictions. Here is an updated summary:
s.13,s.16

Page 41

Withheld pursuant to/removed as

s.16;s.13

Barry, Brittany JR HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Wednesday, December 13, 2017 11:10 AM
To: Bouma, Susan HLTH:EX; Moneo, Mitch HLTH:EX; Fazlagic, Tijana HLTH:EX
Subject: FW: Coverage of Canakinumab
Attachments: 20171213092033338.pdf

FYI – Letter dated Dec 11

From: Elizabeth Liang [<mailto:Elizabeth@porte.ca>]
Sent: Wednesday, December 13, 2017 10:56 AM
To: Lun, Eric HLTH:EX
Subject: Coverage of Canakinumab

Good Morning Mr. Lun,

Attached, for your information and review, is a copy of a letter from David Porte addressed to Premier John Horgan and Minister Adrian Dix, the contents of which are self-explanatory.

Sincerely,

Elizabeth Liang
Executive Assistant to David Porte



100-33 East 8th Avenue
Vancouver, BC V5T 1R5

T 604.732.7651 ext. 110
F 604.732.4673
www.porte.ca elizabeth@porte.ca





December 11, 2017

By e-mail: premier@gov.bc.ca
adrian.dix.MLA@leg.bc.ca

The Honourable Premier John Horgan
P.O. Box 9041 Stn Prov Govt
Victoria, BC V8W 9E1

The Honourable Minister Adrian Dix
Room 337 Parliament Buildings
Victoria, BC V8V 1X4

Dear Premier Horgan and Minister Dix:

Re: Coverage of Canakinumab

I am the Founder and Chairman of Cassie & Friends Society, a Vancouver-based national charity working to transform the lives of children and families affected by Juvenile Arthritis and other rheumatic diseases. I'm writing to alert you to the story of s.22 who is living with systemic juvenile idiopathic arthritis (SJIA) - a severe subset of juvenile idiopathic arthritis (JIA). I would like to meet with you to discuss the impact the BC Government is having on s.22 with SJIA by denying reimbursement coverage for canakinumab (brand name, Ilaris), a medication that is vitally important in the treatment of this severe form of childhood arthritis.

JIA affects approximately 24,000 infants to teens in Canada, or 3 in every 1,000, making it one of the most common causes of chronic disability in children. Ten to 20 percent of children with JIA have Systemic Juvenile Idiopathic Arthritis (SJIA), a severe and potentially life-threatening form of the disease more challenging to diagnose and treat than other types of JIA. Both JIA and SJIA can be devastating and come with high financial, family and societal burdens. Approximately 60% of children will have active disease into adulthood.

s.22

There is an urgent need for the BC government to do more for^{s.22} and the small number of children with severe SJIA who need reimbursement access to canakinumab, currently not covered by BC PharmaCare.

s.22 Today, there are treatments available that can prevent the long-term damage and disability caused by JIA and help children lead a full and active life. New biologic targeted treatments, have revolutionized the care and outcomes for many children with JIA. Today, the "new normal" for children living with JIA means thriving in the classroom and playing sports outdoors, rather than being housebound in a wheelchair, completely isolated from all the things that make up a person's childhood.

Canakinumab is a biologic medication that targets the specific immune dysfunction we now know is causing the severe symptoms of SJIA. An international treatment trial of canakinumab for children with SJIA showed it to be extremely effective in stopping disease symptoms and allowing rapid discontinuation of other medications, like steroids, which result in intolerable side effects to kids. The other major benefit of canakinumab is that it is given by a once-monthly injection, which is easy to tolerate in the young children who need it, some as young as 2 years old. The comparator medication for SJIA requires a daily, excruciatingly painful injection which can be extremely stressful, or even impossible for families of young children to administer.


s.22

Canakinumab has been approved by Health Canada, but currently is not covered by BC Pharmacare. This medication is available on application for children with SJIA in Ontario and Nova Scotia, based on entry criteria designed in collaboration with pediatric rheumatologists. Coverage for this medication through extended health insurance is variable, and therefore sets up a situation in BC that disadvantages children whose families do not have extended insurance, resulting in poor quality care and bad patient outcomes.

s.22

I will contact you in the coming days to get your feedback on this important issue and to arrange a meeting in the next few weeks, whether in person or on the phone. In the meantime, please don't hesitate to contact me by email at david@porte.ca or by phone,^{s.22}

Sincerely,


David Porte
Founder and Chairman
Cassie and Friends Society

Barry, Brittany JR HLTH:EX

From: Gordon, Jason HLTH:EX
Sent: Monday, December 18, 2017 3:34 PM
To: Lun, Eric HLTH:EX; Hodges-Whittaker, Diane HLTH:EX
Cc: Bouma, Susan HLTH:EX; Fazlagic, Tijana HLTH:EX; Gordon, Jason HLTH:EX
Subject: RE: DBC RnR on Canakinumab for sJIA - Check please

I am not sure they are helpful in terms of any sort of resolution, but I also scanned through the American College of Rheumatology guidelines for SJIA below:

<https://www.rheumatology.org/Portals/0/Files/2013%20Update%20of%20the%202011%20ACR%20Recommendations%20for%20the%20Treatment%20of%20Juvenile%20Idiopathic%20Arthritis.pdf>

I was wanting to compare that info to the information we had in Up to Date and our own experiences. Anti-TNF's, rituximab and abatacept, as well as alternate oral options like leflunomide and cyclosporine have all been used, but there is varying levels of evidence and all are thought to work appreciably more poorly than anakinra or canakinumab.

If you notice something I didn't, please let me know! I have not found any clear alternate choices if a person can't take anakinra.

Jason

From: Lun, Eric HLTH:EX
Sent: Monday, December 18, 2017 3:14 PM
To: Hodges-Whittaker, Diane HLTH:EX
Cc: Bouma, Susan HLTH:EX; Fazlagic, Tijana HLTH:EX; Gordon, Jason HLTH:EX
Subject: RE: DBC RnR on Canakinumab for sJIA - Check please

Thanks Diane – Please also check the CPR reports. I'm copying Jason Gordon as well.

Eric

From: Hodges-Whittaker, Diane HLTH:EX
Sent: Monday, December 18, 2017 3:12 PM
To: Lun, Eric HLTH:EX
Cc: Bouma, Susan HLTH:EX; Fazlagic, Tijana HLTH:EX
Subject: RE: DBC RnR on Canakinumab for sJIA - Check please

Hí, Eric

So far I have found the following information in the CDR Clinical Review Report for canakinumab:

Other recommended treatment options include the disease-modifying antirheumatic drug (DMARD) methotrexate or a biologic agent.^{5,6} In clinical practice however, the role of these agents is evolving, as some references even question their effectiveness for the systemic subtype of JIA.^{8,11,20} **Methotrexate** is the most widely used DMARD in clinical practice.^{3,21} Potential adverse events of importance include liver and pulmonary toxicities, hematologic abnormalities and malignancies.^{3,21} Biologic agents include **TNF α -inhibitors** (adalimumab, etanercept and infliximab) and the **T-cell inhibitor** abatacept. These may be used in the absence of systemic features only. Drawbacks include the absence of a Health Canada indication for the systemic subtype of JIA, limited availability of long-term safety data in children, as well as concerns regarding potential serious toxicities including increased risk of infections, autoimmune disorders and pediatric malignancies.²²⁻²⁵

I am still looking for other references.

Cheers,

Diane Hodges-Whittaker
Drug Formulary Policy Analyst
Drug Intelligence and Optimization
Pharmaceutical Services Division
Ministry of Health

PO BOX 9652 STN PROV GOVT | V8W 9P4
(250) 952-2271 | Diane.HodgesWhittaker@gov.bc.ca

From: Lun, Eric HLTH:EX
Sent: Monday, December 18, 2017 2:41 PM
To: Fazlagic, Tijana HLTH:EX; Hodges-Whittaker, Diane HLTH:EX
Cc: Bouma, Susan HLTH:EX
Subject: DBC RnR on Canakinumab for sJIA - Check please

Tijana and Diane – can you please track back to the Ilaris (canakinumab) recommendation for sJIA and advise where the bolded statement originated from? Did it come from DBC or CPR or somewhere else?

Sorry but we need to confirm asap as we're working on an active case request.

Excerpt from the 2016 DBC report in regards to the latter

- ***Adalimumab (Humira), abatacept (Orencia), etanercept (Enbrel) and infliximab (Remicade) are all biologics which are not indicated for sJIA but can potentially be used for treatment of sJIA. They are all Limited Coverage benefits for indications other than sJIA and have pediatric rheumatologist exemptions.***
- *The comparator drug, kineret (Anakinra) is not indicated for sJIA; however, as noted by the clinical expert in the Common Drug Review (CDR) report, it is often prescribed to patients with sJIA. It is not an eligible PharmaCare benefit. In British Columbia, kineret (Anakinra) is provided to patients with sJIA on an exceptional case-by-case scenario.*
- *Other comparator drugs that are used as supportive care for sJIA, but do not have an approved indication, are methotrexate and prednisone which are Regular Benefits.*

Barry, Brittany JR HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Monday, December 18, 2017 4:43 PM
To: Hodges-Whittaker, Diane HLTH:EX; Bouma, Susan HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Gordon, Jason HLTH:EX
Subject: RE: DBC RnR on Canakinumab for sJIA - Check please

Thanks Diane

Sue/Jason – these other options, albeit off label, seem to be appropriate options for the patient to consider given that canakinumab is not a PC benefit.

Eric

From: Hodges-Whittaker, Diane HLTH:EX
Sent: Monday, December 18, 2017 3:36 PM
To: Lun, Eric HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Bouma, Susan HLTH:EX; Gordon, Jason HLTH:EX
Subject: FW: DBC RnR on Canakinumab for sJIA - Check please

Hi, Eric

I found the following table in the CDR Pharmacoeconomic Report. I think it should be useful for you.

The treatment options presented in the tables below have been deemed to be appropriate by clinical experts for the treatment of patients with sJIA. Comparators may be recommended (appropriate) practice, versus actual practice. Comparators are not restricted to drugs, but may be devices or procedures. Existing Product Listing Agreements are not reflected in the table and as such may not represent the actual costs to public drug plans...

TABLE 6. OTHER POTENTIAL TREATMENTS FOR SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (TNF INHIBITORS) – NOT INDICATED

Drug/ Comparator	Strength	Dosage Form	Price (\$)	Recommended Dose	Average Annual Drug Cost (\$)
Adalimumab (Humira)	40 mg/0.8 mL	Vial of sterile solution for SC injection	740.3600	Age 2 to Age 4 to 17: 40 mg every 2 weeks	19,249
Abatacept (Orencia)	250 mg/15 mL	Vial for IV infusion	490.0470	Patients a	20 to 60 kg:b 6,371 to 19,112
Etanercept (Enbrel)	50 mg/mL 25 mg/vial	Pre-filled syringe Powder for reconstitution	395.3900 197.6350	0.8 mg/kg (max 50 mg) per weekc	16 to 60 kg:d 10,277 to 20,554
Infliximab (Remicade)	100 mg/vial	Injection for IV infusion	987.5600	3 mg/kg every 8 weeksf	33 kg or below: 6,419 34 to 60 kg: 12,838

I also checked both of the Clinical Practice Reports but found little of interest regarding your question. The most on-point is the following excerpt from the Specialist 2 report:

The comparator arm in the cost-utility analysis of Canakinumab **as second line biologic** was stated as methotrexate (1 mg per Kg per week) and prednisone (1 mg per Kg per day). This is an artificial comparison, as no prudent physician would maintain those doses of medications and do nothing else while facing a child with

ongoing active systemic JIA. The most likely scenario (although one very difficult to model) is that the physician will try in succession whatever other options are available, such as anakinra, intravenous immunoglobulin, cyclosporine, abatacept or tumour necrosis factor inhibitors; all of which are considerably more expensive than methotrexate and prednisone alone.

Let me know if you need anything further.

Cheers,

Diane Hodges-Whittaker
Drug Formulary Policy Analyst
Drug Intelligence and Optimization
Pharmaceutical Services Division
Ministry of Health

PO BOX 9652 STN PROV GOVT | V8W 9P4
(250) 952-2271 | Diane.HodgesWhittaker@gov.bc.ca

From: Hodges-Whittaker, Diane HLTH:EX
Sent: Monday, December 18, 2017 3:12 PM
To: Lun, Eric HLTH:EX
Cc: Bouma, Susan HLTH:EX; Fazlagic, Tijana HLTH:EX
Subject: RE: DBC RnR on Canakinumab for sJIA - Check please

Hi, Eric

So far I have found the following information in the CDR Clinical Review Report for canakinumab:

Other recommended treatment options include the disease-modifying antirheumatic drug (DMARD) methotrexate or a biologic agent.^{5,6} In clinical practice however, the role of these agents is evolving, as some references even question their effectiveness for the systemic subtype of JIA.^{8,11,20} **Methotrexate** is the most widely used DMARD in clinical practice.^{3,21} Potential adverse events of importance include liver and pulmonary toxicities, hematologic abnormalities and malignancies.^{3,21} Biologic agents include **TNF α -inhibitors** (adalimumab, etanercept and infliximab) and the **T-cell inhibitor** abatacept. These may be used in the absence of systemic features only. Drawbacks include the absence of a Health Canada indication for the systemic subtype of JIA, limited availability of long-term safety data in children, as well as concerns regarding potential serious toxicities including increased risk of infections, autoimmune disorders and pediatric malignancies.²²⁻²⁵

I am still looking for other references.

Cheers,

Diane Hodges-Whittaker
Drug Formulary Policy Analyst
Drug Intelligence and Optimization
Pharmaceutical Services Division
Ministry of Health

PO BOX 9652 STN PROV GOVT | V8W 9P4
(250) 952-2271 | Diane.HodgesWhittaker@gov.bc.ca

From: Lun, Eric HLTH:EX
Sent: Monday, December 18, 2017 2:41 PM
To: Fazlagic, Tijana HLTH:EX; Hodges-Whittaker, Diane HLTH:EX
Cc: Bouma, Susan HLTH:EX
Subject: DBC RnR on Canakinumab for sJIA - Check please

Tijana and Diane – can you please track back to the Ilaris (canakinumab) recommendation for sJIA and advise where the bolded statement originated from? Did it come from DBC or CPR or somewhere else?

Sorry but we need to confirm asap as we're working on an active case request.

Excerpt from the 2016 DBC report in regards to the latter

- ***Adalimumab (Humira), abatacept (Orencia), etanercept (Enbrel) and infliximab (Remicade) are all biologics which are not indicated for sJIA but can potentially be used for treatment of sJIA. They are all Limited Coverage benefits for indications other than sJIA and have pediatric rheumatologist exemptions.***
- *The comparator drug, kineret (Anakinra) is not indicated for sJIA; however, as noted by the clinical expert in the Common Drug Review (CDR) report, it is often prescribed to patients with sJIA. It is not an eligible PharmaCare benefit. In British Columbia, kineret (Anakinra) is provided to patients with sJIA on an exceptional case-by-case scenario.*
- *Other comparator drugs that are used as supportive care for sJIA, but do not have an approved indication, are methotrexate and prednisone which are Regular Benefits.*

Barry, Brittany JR HLTH:EX

From: Stevens, Sandy HLTH:EX
Sent: Tuesday, December 19, 2017 12:51 PM
To: Fazlagic, Tijana HLTH:EX
Subject: FW: 1077443 - can i get a copy of the
Attachments: SR0463 Ilaris sJIA - Final Clinical Review Report May 27, 2016.pdf; canakinumab (Ilaris) 3452 DBC DRS FINAL 2016 Jul 04.pdf; canakinumab (Ilaris) 3452 DBN.PDF

Can this BN be embedded into Cliff?

Cheers
Sandy

From: HLTH Corporate Operations HLTH:EX
Sent: Tuesday, December 19, 2017 12:45 PM
To: Stevens, Sandy HLTH:EX; McClymont, Brenda HLTH:EX
Cc: HLTH Corporate Operations HLTH:EX
Subject: 1077443 - can i get a copy of the

Should this BN be embedded in cliff?

Thanks,
Kathy

From: Will, Jordan HLTH:EX
Sent: Tuesday, December 19, 2017 10:42 AM
To: Singh, Jasmyn HLTH:EX
Cc: Lun, Eric HLTH:EX; Stearn, Anne HLTH:EX; Fougere, Brianna HLTH:EX; HLTH Corporate Operations HLTH:EX
Subject: 1077443 - can i get a copy of the

Hi Jasmyn,

As per your request, please find the DBN as well as additional supporting information provided by Pharmaceutical Services Division

Thank you,

JORDAN WILL
Director, Executive Operations
Office of the Deputy Minister
Ministry of Health

P: 250.952.1908 | Jordan.Will@gov.bc.ca

Drug Benefit Council (DBC)

Drug Review Summary

canakinumab (Ilaris®)

Question for Consideration (DBC)

1. Based on the evidence provided, what is your recommendation to the British Columbia Ministry of Health (the Ministry) regarding the PharmaCare coverage status of canakinumab (Ilaris®) for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients aged 2 years and older?

Issues for Consideration

- On December 12, 2013, canakinumab, manufactured by Novartis Pharmaceuticals Canada Inc. was granted a Notice of Compliance for the treatment of active sJIA in patients aged 2 years and older.
- On May 27, 2016, the Canadian Drug Expert Committee (CDEC) recommended (*EMBARGOED*) that canakinumab be reimbursed for the treatment of active sJIA in patients aged 2 years and older with the following criteria and conditions:

Clinical Criteria

- Patients who have had an inadequate response or intolerance to oral steroids or methotrexate.
- Treatment to be discontinued if there is no improvement after day 15.

Conditions

- Price should not exceed the drug plan cost of tocilizumab (Actemra).
- Patients should be under the care of a physician with experience in treating sJIA.
- The CDEC noted that there is insufficient evidence to determine whether canakinumab would still be an effective treatment for patients who have previously discontinued treatment with other biologic agents, including tocilizumab, due to lack of efficacy or intolerance.
- Canakinumab (Ilaris®) is also indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) which was reviewed by the Common Drug Review (CDR) in 2011 with a recommendation not to list. The Ministry provides coverage for one patient for this condition through the Expensive Drugs for Rare Diseases (EDRD) program.
- Tocilizumab Intravenous Formulation (IV) (Actemra) is indicated for sJIA in patients 2 years of age and older who have responded inadequately to previous therapy with Disease Modifying Anti-Rheumatic Drugs (DMARDs) and is a Limited Coverage benefit with the following criteria:
 - For the treatment of active sJIA in patients two years of age and older who, due to intolerance or lack of efficacy, have not adequately responded to: non-steroidal anti-

inflammatory drugs (NSAIDs) AND systemic corticosteroid drugs (with or without methotrexate).

- Adalimumab (Humira), abatacept (Orencia), etanercept (Enbrel) and infliximab (Remicade) are all biologics which are not indicated for sJIA but can potentially be used for treatment of sJIA. They are all Limited Coverage benefits for indications other than sJIA and have pediatric rheumatologist exemptions.
- The comparator drug, kineret (Anakinra) is not indicated for sJIA; however, as noted by the clinical expert in the Common Drug Review (CDR) report, it is often prescribed to patients with sJIA. It is not an eligible PharmaCare benefit. In British Columbia, kineret (Anakinra) is provided to patients with sJIA on an exceptional case-by-case scenario.
- Other comparator drugs that are used as supportive care for sJIA, but do not have an approved indication, are methotrexate and prednisone which are Regular Benefits.
- The Patient Input report and Manufacturer's Comments to the Clinical Practice Reports will be available on the DBC SharePoint site.

Generic name/Brand Name®)
canakinumab (Ilaris®)

Dosage Forms/Strengths

150 mg vial of powder for solution for subcutaneous injection

Manufacturer

Novartis Pharmaceuticals Canada Inc.

Health Canada Approved Indications

Canakinumab (Ilaris®) has the following Health Canada indications:

- for the treatment of active sJIA in patients aged 2 years and older
- Cryopyrin-Associated Periodic Syndromes (CAPS): Familial Cold Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FCU); and Muckle-Wells Syndrome (MWS).
- Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA).

Manufacturer's Request

Novartis Pharmaceuticals Canada Inc. is requesting reimbursement of canakinumab for the treatment of active sJIA in patients aged 2 years and older who are contraindicated to, or have discontinued, any biologic therapy for lack of efficacy or intolerance.

Disease state overview

Juvenile idiopathic arthritis (JIA) is a chronic rheumatic disorder diagnosed in children 16 years of age or younger, primarily affecting joints.

Systemic onset JIA is subtype of JIA recognized by the International League of Associations for Rheumatology (ILAR) accounting for approximately 4% to 15% of patients with JIA.

sJIA is defined as arthritis in one or more joints for at least 6 weeks in a child younger than 16 years with or preceded by fever of at least 2 weeks that is documented to be daily for at least 3 days and accompanied by one or more of the following: evanescent erythematous rash, generalized lymphadenopathy, hepatomegaly or splenomegaly, and serositis. The clinical experts consulted indicated that sJIA is characterized by an intense inflammatory state; several patients present with a particularly refractory course, associated with persistent disease. As a result, these patients are at high risk for serious complications such as joint damage and growth impairment.

Patients with sJIA are also at particular high risk of developing macrophage activation syndrome (MAS), a life-threatening complication characterized by an overwhelming inflammatory reaction. Between 10% and 15% of children with sJIA develop overt clinical features of MAS, but an even higher prevalence of subclinical MAS is suspected. The main symptoms of MAS include fever, organomegaly, cytopenias, liver dysfunction, coagulopathy resembling disseminated intravascular coagulation, hyperferritinemia and other laboratory abnormalities. MAS is associated with a mortality rate in children with sJIA that is estimated at 6% in hospitalized patients, but may be overall as high as 20% according to various references. (Please see Common Drug Review Clinical Report on page 11 of 88.)

Comparative Cost of Therapy and Current Coverage Status of Comparators Drugs with 5% mark up (unless otherwise noted)						
Drug / Comparator	Strength	Dosage Forms	PharmaCare Status	Cost/ Unit	Recommended Daily Dose	Annual Cost of Therapy
canakinumab (Ilaris)	150 mg	Vial of powder for sol. for SC injection	Under Review	\$16,800	Body weight> 9 kg, 4mg/kg (max 300 mg) every 4 weeks	≤ 37kg :\$218,400
						≥ 38kg: \$436,800
tocilizumab (Actemra)	80 mg/4 ml	Vials (concentrate sol. for IV infusion)	Limited coverage	\$189.45	Patients < 30kg: 12mg/kg every 2 weeks	12 to 29 kg ¹ : \$8,866 - \$21,427
	200 mg/10 ml			\$473.63	Patients ≥ 30kg: 8 mg/kg every 2 weeks	30 kg ¹ or above: \$14,777 - \$29,555
	400 mg/20 ml			\$947.26		
Other potential treatments of sJIA– NOT INDICATED						
anakinra (Kineret)	100 mg	Prefilled syringe for SC injection	Non-Benefit	\$47,58 ²	100 mg daily	\$17,367 ²
adalimumab (Humira)	40 mg/0.8ml	Vial of sterile sol. for SC injection	Limited Coverage (not for sJIA)	\$800.70	Age 2 to < 4: 20 mg every 2 weeks	\$20,818
					Age 4 to 17: 40mg every 2 weeks	

Comparative Cost of Therapy and Current Coverage Status of Comparators Drugs with 5% mark up (unless otherwise noted)						
Drug / Comparator	Strength	Dosage Forms	PharmaCare Status	Cost/ Unit	Recommended Daily Dose	Annual Cost of Therapy
abatacept (Orencia)	250 mg/15 ml	Vial for IV infusion	Limited Coverage (<i>not for sJIA</i>)	\$514.54	Pts < 75kg: 10mg/kg every 4 weeks	20 to 60 kg ³ : \$6,689 - \$20,067
					Pts ≥75 kg (max 1000mg) every 4 weeks	
etanercept (Enbrel)	50 mg/ml	Pre-filled syringe	Limited Coverage (<i>not for sJIA</i>)	\$382.49	0.8 mg/kg (max 50mg) per week	\$20,272 ⁴
infliximab (Remicade)	100 mg/vial	Injection for IV infusion	Limited Coverage (<i>not for sJIA</i>)	\$1,036.94	3 mg/kg every 8 weeks	33 kg or below: \$6,662
						34 to 60 kg: \$12,128
Treatments used for supportive care for sJIA – NOT INDICATED						
methotrexate (generics)	2.5 mg	Tablet	Regular Benefit	\$0.68	1 mg/kg weekly	Oral: \$723 ⁵
	10 mg			\$2.32		
	10 mg/ml	Single-use vial	Limited Coverage(<i>not for sJIA</i>)	\$6.19		
	25 mg/ml			\$6.08		
prednisone (generics)	1 mg	Tablet	Regular benefit	\$0.12	1 mg/kg weekly	Based on 60 kg patient: \$21 ⁵
	5 mg			\$0.04		
	50 mg			\$0.37		
¹ Tocilizumab is listed for patients aged 2 years or older. The average weight of 2 year olds in Canada is 12kg, and the average weight of 17 year olds in Canada is 60 kg. ² Price as per CDR Report ³ Abatacept is listed for patients aged 6 years or older. The average weight of 6 year olds in Canada is 20 kg, and the average weight of 17 year olds is Canada is 60 kg. ⁴ Etanercept is listed for patients 4 years or older. The average weight of 4 year olds in Canada is 16 kg, and the average weight of 17 year olds in Canada is 60 kg. ⁵ 8% mark-up added						
SC: Subcutaneous; sol: solution; IV: intravenous; recon: reconstitution; Pts: Patients						

Key Outcome Measures

Primary Outcomes

- American College of Rheumatology Pediatric response (ACR Pedi)
- Disease activity including but not limited to:
 - Absence of systemic features
 - Number of joints affected
 - Absence of disease flares
 - Steroid tapering
- Health-related quality of life
- Functional and disability outcomes
- Pain reduction measured on a validated scale
- Patient's or parents' treatment satisfaction

Harms

- Mortality
- Serious adverse events
- Withdrawals due to adverse events
- Adverse events including but not limited to:
 - Serious infections
 - Neutropenia
 - Pediatric malignancies
- Notable complications including but not limited to:
 - Abnormalities of growth
 - Macrophage activation syndrome
 - Uveitis

Patent Expiry Date

August 20, 2021

Data Protection Date

Data protection expires on August 26, 2018

Known Unapproved or Potential Indications for Use

None

Adverse Drug Reaction Reporting from Health Canada

23 adverse reactions were reported in the period December 12, 2013 to December 31, 2015.

Health Canada Issues

None reported as of May 31, 2016.

Miscellaneous Issues

In August 2013, The National Institute for Health and Care Excellence (NICE) advised to include the canakinumab for the treatment of active sJIA in patients 2 years and older who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids.

In October 2014, the U.S. Food and Drug Administration released the following safety advisory for canakinumab: Serious infections, predominantly of the upper respiratory tract, in some instances serious, have been reported with ILARIS. Generally, the observed infections responded to standard therapy. Isolated cases of unusual or opportunistic infections (e.g., aspergillosis, atypical mycobacterial infections, cytomegalovirus, herpes zoster) were reported during ILARIS treatment

**MINISTRY OF HEALTH
DECISION BRIEFING NOTE**

Cliff # 1077443

PREPARED FOR: Tijana Fazlagic, Director - **FOR DECISION**

TITLE: Drug Review Listing Decision for canakinumab (Ilaris®) for the treatment of active Systemic Juvenile Idiopathic Arthritis in patients aged two years and older.

PURPOSE: To make a drug review listing decision for the submission of canakinumab (Ilaris®) for the treatment of active Systemic Juvenile Idiopathic Arthritis in patients aged two years and older.

BACKGROUND:

- Canakinumab (Ilaris), manufactured by Novartis Pharmaceuticals Canada Inc., was submitted to the Ministry of Health (the Ministry) requesting that the drug be listed as a PharmaCare Limited Coverage benefit for the treatment of active Systemic Juvenile Idiopathic Arthritis (sJIA) in patients aged two years and older in whom other biologic treatments are contraindicated or who have discontinued any biologic therapy for lack of efficacy or intolerance.
- On June 17, 2016, the Canadian Drug Expert Committee (CDEC) recommended that canakinumab be reimbursed for the treatment of sJIA in patients two years and older with the following clinical criteria and conditions including that cost should not exceed the drug plan cost of tocilizumab (Appendix 1).
- In July 2016, the Drug Benefit Council (the Council) recommended that canakinumab not be listed at the submitted price (Appendix 2).
- Canakinumab is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS). The Ministry provides coverage for s.22 for this condition through the Expensive Drugs for Rare Diseases (EDRD) program.
- Intravenous tocilizumab (Actemra®) is an eligible PharmaCare Limited Coverage benefit for sJIA in patients two years of age and older who have not adequately responded to non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroid drugs (with or without methotrexate). Practitioner exemptions are available to pediatric rheumatologists for this drug.
- Adalimumab (Humira®), abatacept (Orencia®), etanercept (Enbrel®) and infliximab (Remicade® or Inflectra™) are not indicated for sJIA, but may potentially be used for the treatment of sJIA. These biologics are Limited Coverage benefits for indications other than sJIA and most have practitioner exemptions for pediatric rheumatologists.
- Anakinra (Kineret®) is not indicated for sJIA, but is often used in for this condition (as per a clinical expert in the CDR report). Anakinra is not an eligible PharmaCare benefit; however, in FY15/16, PharmaCare provided coverage of anakinra to s.22 for sJIA on an exceptional case-by-case basis.
- Methotrexate and prednisone are used as supportive care in sJIA and are PharmaCare Regular Benefits.

DISCUSSION:

- In their review, the Council considered the following: the final reviews completed by the CDR on June 17, 2016, which included clinical and pharmacoeconomic evidence

review material and the recommendations from the CDEC. The DBC also considered Patient Input Questionnaire responses from one patient, five caregivers, and one Patient Group, CDR Patient Group input, Clinical Practice Reviews from two specialists, and a Budget Impact Assessment.

- In two double blind, placebo-controlled, randomized controlled trials (RCTs), canakinumab was superior to placebo in achieving a treatment response, was associated with a significant reduction in the risk of a disease flare and was associated with a reduced risk of disease worsening and a higher likelihood of inactive disease.
- There are no direct comparisons for canakinumab versus other treatments for sJIA. The CDEC noted that indirect comparisons suggest that canakinumab has similar efficacy to other biologic therapies used to treat sJIA. There is also insufficient evidence that canakinumab should be used if treatment intolerance or failure occur on other biologics (Appendix 1).
- At the submitted price, the annual cost canakinumab is 10 to 15 times higher than other treatments for sJIA.
- The pan-Canadian Pharmaceutical Alliance (pCPA) and Novartis agreed not to proceed with price negotiations. Novartis was unable to provide value that met the mandate established by the pCPA which is cost similar to the treatment with tocilizumab.

FINANCIAL IMPLICATIONS:

s.13,s.17

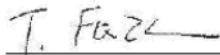
OPTIONS:

Option 1: Effective January 10, 2017, do not list canakinumab (Ilaris) for the treatment of sJIA in patients aged two years and older.

s.13,s.17

RECOMMENDATION:

Option 1



Approved

Tijana Fazlagic

Director, Formulary Management

January 10, 2017

Date Signed

Program ADM/Division:

Telephone:

Program Contact (for content):

Drafter:

Date:

File Name with Path:

DBN.dotx

Barbara Walman, Medical Beneficiary & Pharmaceutical Services Division

250 952-1464

Eric Lun

Diane Lee

January 5, 2017

[https://healthshare.gov.bc.ca/prod/Documents/13006/canakinumab \(Ilaris\) 3452](https://healthshare.gov.bc.ca/prod/Documents/13006/canakinumab%20(Ilaris)%203452)

Appendix 1



CADTH CANADIAN DRUG EXPERT COMMITTEE FINAL RECOMMENDATION

CANAKINUMAB
(Ilaris — Novartis Pharmaceuticals Canada Inc.)
Indication: Systemic Juvenile Idiopathic Arthritis

Copyright

Page 60 to/à Page 64

Withheld pursuant to/removed as

Copyright

Appendix 2

Drug Benefit Council (DBC) Recommendation and Reasons for Recommendation

FINAL

Canakinumab (Ilaris®)
Novartis Pharmaceuticals Canada Inc.

Description:

Drug review of **canakinumab (Ilaris®)** for the following Health Canada approved indication:

For the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients aged 2 years and older

In their review, the DBC considered the following: the final reviews completed by the Common Drug Review (CDR) on June 17, 2016, which included clinical and pharmacoeconomic evidence review material and the recommendations from the Canadian Drug Expert Committee (CDEC). The DBC also considered Patient Input Questionnaire responses from one patient, five caregivers, and one Patient Group, CDR Patient Group input, Clinical Practice Reviews from two specialists, and a Budget Impact Assessment.

Dosage Forms:

Ilaris® is available as canakinumab 150 mg vial of powder for solution for subcutaneous injection.

Recommendations:

1. The Drug Benefit Council (DBC) recommends that canakinumab (Ilaris®) not be listed at the submitted price.

Reasons for the Recommendation:

1. Summary

In two double blind placebo-controlled randomized controlled trials (RCTs), canakinumab was superior to placebo in achieving a treatment response in patients with sJIA, was associated with a significant reduction in the risk of a disease flare

- compared with placebo, and was associated with a reduced risk of disease worsening and a higher likelihood of inactive disease compared with placebo.
- Canakinumab was associated with a statistically and clinically significant improvement in quality of life, reduced pain and improved functionality compared to placebo in one study.
- There are no direct comparisons for canakinumab versus other treatments for sJIA.
- At the submitted price, the annual cost canakinumab is 10 to 15 times higher than other treatments for sJIA.

2. Clinical Efficacy

- The DBC considered the CDR systematic review of canakinumab, which included two published, manufacturer-sponsored, double blind placebo-controlled RCTs.
- Study 2301 evaluated the superiority of canakinumab compared to placebo based on the primary outcome of time to flare events, using a flare prevention design (randomized treatment withdrawal in responders). Canakinumab was associated with a statistically significant reduction in the risk of a disease flare compared to placebo in patients who previously achieved a minimum response with the drug, was superior to placebo in reducing the risk of a worsening in adapted American College of Rheumatology Pediatric (ACR Pedi) response level throughout the study duration, and was associated with a statistically significantly higher likelihood of inactive disease compared with placebo.
- Study 2305 evaluated the superiority of canakinumab compared with placebo based on the proportion of patients who achieved at least an adapted ACR Pedi 30 response at day 15 and were followed-up for a total of four weeks.
- Study 2305 demonstrated the superiority of canakinumab over placebo in order to achieve an adapted ACR Pedi 30 response after 15 days of treatment in patients with sJIA. Patients receiving canakinumab were also statistically significantly more likely to achieve an adapted ACR Pedi 90 response or an adapted ACR Pedi 100 response after 30 days of treatment.
- In Study 2305, canakinumab was associated with a statistically significant and clinically meaningful benefit compared to placebo in relation to health-related quality of life, pain, and functionality after 29 days of treatment.
- There are no direct comparisons for canakinumab versus other treatments for sJIA.
- There is insufficient evidence to determine whether canakinumab would be an effective treatment for patients who have previously discontinued treatment with other biologic drugs, including tocilizumab, due to a lack of efficacy or intolerance.
- For detailed information on the systematic review of canakinumab (Ilaris®), please see the CDEC Final Recommendation at:
https://www.cadth.ca/sites/default/files/cdr/complete/SR0463_complete_Ilaris_sJIA_June_21_16_e.pdf.

3. Safety

- No deaths were reported in Study 2305. Deaths during Study 2301 were reported for one patient each in the canakinumab and placebo groups, both due to macrophage activation syndrome (MAS).
- At least one serious adverse event (SAE) was reported for 5% of patients in both canakinumab and placebo groups in Study 2305. In Study 2301, during the double-blind phase, SAEs were reported for 12% of patients in both groups. The most commonly reported SAEs were MAS and juvenile arthritis.
- SAEs related to infection were infrequent. MAS was less common among canakinumab-treated patients compared with placebo-treated patients.
- In Study 2305, at least one adverse event (AE) was reported for 56% of patients in the canakinumab group and 39% of patients in the placebo group. In Study 2301, 80% of patients in the canakinumab group experienced AEs compared with 70% in the placebo group. The most commonly reported AEs were arthralgia, cough, nasopharyngitis, pyrexia, upper respiratory tract infection, abdominal pain, and pain in an extremity.
- Due to the short duration of the trials there is insufficient evidence regarding the long-term safety of canakinumab.
- For detailed information on the safety and tolerability of canakinumab (Ilaris®), please see the CDEC Final Recommendations at the link above.

4. Economic Considerations

- The DBC considered the CDR Pharmacoeconomic Review, which consisted of a re-analysis of the manufacturer's submitted cost-utility analysis to address some of the submission's limitations.
- For second-line biologic treatment (as per the reimbursement request), the CDR best estimate of the incremental cost utility ratio (ICUR) ranged from \$459,000 to \$1,584,000 per quality adjusted life year (QALY) for canakinumab compared with best supportive care (BSC), or \$171,000 to \$591,000 per QALY when considering the manufacturer's proposed risk-sharing agreement.
- At the submitted price, the annual cost of canakinumab is substantially higher than that of tocilizumab.

5. Of Note

- The DBC considered Patient Input Questionnaire responses from one patient, five caregivers, and one Patient Group. Patient and caregivers described how sJIA is a serious, disabling and chronic condition that can cause irreversible damage. Some patients may require major joint surgery, including joint replacement or fusion. Patients may experience growth retardation, intense inflammation, serious pain, and fatigue. Effects of sJIA can also be psychological, as patient may be unable to play like other children, have difficulty sleeping, walking, and taking part in school or recreational activities. Significant costs associated with sJIA include medical appointments, needles, syringes, and the cost of concurrent treatments (NSAIDs, corticosteroids, and DMARDs). Patients and caregivers noted that treatment responses vary among patients, and current therapies are associated with serious AEs. The injection pain associated with another sJIA treatment, anakinra, was noted.
- The DBC supported the CDEC recommendation that the drug plan cost for canakinumab should not exceed the cost of tocilizumab.

Barry, Brittany JR HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Wednesday, December 20, 2017 1:46 PM
To: Moneo, Mitch HLTH:EX; Bouma, Susan HLTH:EX; Fazlagic, Tijana HLTH:EX
Subject: Fw: Canakinumab Coverage for SJIA - Parent/Constituent Letter & Testimonials
Attachments: canikinumab letter.pdf

Fyi

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization
Pharmaceutical Services Division
BC Ministry of Health

From: Jennifer Wilson
Sent: Wednesday, December 20, 2017 13:29
To: Minister, HLTH HLTH:EX; Lun, Eric HLTH:EX
Cc: Horgan.MLA, John LASS:EX; David Porte; Thorntthwaite.MLA, Jane LASS:EX; Rosanne Kyle
Subject: Canakinumab Coverage for SJIA - Parent/Constituent Letter & Testimonials

Dear Honourable Minister Dix and Mr. Eric Lun of BC Pharmacare,

In follow-up to David Porte's meeting request of Dec 17 (below) and my phone call to Mr. Dix's office yesterday, **please find attached another letter from a Cassie & Friends Society** s.22
s.22

s.22

We hope you will act quickly to understand this issue through the patient stories we have been sharing and meet with us to review evidence-based criteria from leading pediatric rheumatologists in BC for the evaluation of canakinumab access. We are certain you'll agree: children deserve a more personalized and precise approach to treatment for such a severe disease as SJIA.

s.22

We need your help. Please contact us to schedule a meeting immediately to address this critical issue and review our proposed criteria from BC's SJIA medical experts.

Thank you,

Jennifer Wilson
Executive Director
Cassie and Friends Society
jennifer@cassieandfriends.ca
604.617.1382
www.cassieandfriends.ca

----- Forwarded message -----

From: **David Porte** <David@porte.ca>

Date: 17 December 2017 at 22:38

Subject: Canakinumab - Follow up letter.

To: "hlth.minister@gov.bc.ca" <hlth.minister@gov.bc.ca>

Cc: Jennifer Wilson <jennifer@cassieandfriends.ca>, "Premier@gov.bc.ca" <Premier@gov.bc.ca>

To the Honourable Minister of Health, Adrian Dix,

This email is a follow up to my last letter dated December 13th.

I am writing to you today to request a meeting immediately with our organization, Cassie and Friends Society, and yourself to discuss the critical issue of Canakinumab access, as brought to the province's attention by s.22 s.22

I am both the chair of the Cassie and Friends Society s.22 with Juvenile Arthritis. As a lifelong British Columbian, I have dedicated the last ten years to building this organization, which is committed to transforming lives of children and families with Juvenile Arthritis and other rheumatic diseases based on my own family's experience and those of the families we serve.
s.22

The children in our province with Systemic Juvenile Arthritis (SJIA) have the very worst form of Juvenile Arthritis - a potentially life-threatening form - and I think you'd agree, they deserve a childhood also. What is standing in the way of children like s.22
s.22 is access to Canakinumab.

s.22

s.22

Because of this, I understand what these parents must be going through right now. But what I've never had to experience and can't even imagine is what these parents also know: that there is a medication that will help their child that they can't have due to cost, lack of access, lack of private insurance or lack of money. These parents must watch their child suffer unimaginable pain every day - and their only hope is you.

My request is to schedule a meeting immediately with you to address this critical issue. Every day that passes is one more day of pain for the children, one more day of their life robbed from them.

We at Cassie and Friends are available to meet at any time. We will bring to the meeting leading Canadian pediatric rheumatologists, based out of BC Children's Hospital (BCCH) who are willing to immediately work with your office to develop appropriate criteria on which to evaluate children with SJIA on a case-by-case basis for access to Canakinumab. The centre at BCCH is world renown for its contributions to Juvenile Arthritis. The paediatric rheumatologists are specialists in the province that prescribe this medication in the cases when it is needed. They can help explain from a medical perspective why this issue is so critical.

I can be reached either through my office at 604-732-7651 x 105, on my mobile number ^{s.22} or through email at david@porte.ca

Along with all the parents and children that are suffering today because Canakinumab is unavailable to them, I await your call.

David Porte

Cassie & Friends
T 604.732.7651 ext. 105
s.22

www.cassieandfriends.ca | david@porte.ca

December 18, 2017

TO: The Honourable Premier John Horgan
P.O. Box 9041 Stn Prov Govt
Victoria, BC V8W 9E1

TO: The Honourable Minister Adrian Dix (and also my MLA)
Room 337 Parliament Buildings
Victoria, BC V8V 1X4

Re: Coverage of Canakinumab

I'm writing as a resident of British Columbia and constituent of Adrian Dix's riding to strongly request the funding of **canakinumab under BC PharmaCare**.

s.22

s.22

This disease affects a person's joints, and also potentially major organs, including the liver, lungs, skin, eyes and heart. While SJIA is active, whether early on or later in life, inflammation can cause severe and permanent damage to a person's joints and organs.

s.22

JIA affects approximately 24,000 infants to teens in Canada, or 3 in every 1,000, making it one of the most common causes of chronic disability in children. Ten to 20 percent of children with JIA have Systemic Juvenile Idiopathic Arthritis (SJIA), a severe and potentially life-threatening form of the disease more challenging to diagnose and treat than other types of JIA. Both JIA and SJIA can be devastating and come with high financial, family and societal burdens. Approximately 60% of children will have active disease into adulthood.

There is no cure for SJIA. Today, there are treatments available that can prevent the long-term damage and disability caused by JIA and help children lead a full and active life. New biologic targeted treatments, have revolutionized the care and outcomes for many children with JIA. Today, the "new normal" for children living with JIA means thriving in the classroom and playing sports outdoors, rather than being housebound in a wheelchair, isolated from all the things that make up a person's childhood.

s.22

s.22

For other families, the painful daily injections continue.^{s.22}
s.22

Cassie & Friends Society, a Vancouver-based national charity working to transform the lives of children and families affected by Juvenile Arthritis and other rheumatic diseases, is fighting for^{s.22} and other children in similar circumstances to have the once a month medication, Canakinumab, funded by BC Pharmacare. I am aware that Cassie and Friends have been in contact with you previously asking to discuss this matter. The benefits of Canakinumab have been outlined in previous letters from Cassie and Friends, as well as the funding coverage in other provinces as precedent, so I will not reiterate.

s.22

s.22

The current government has the opportunity to support a small group of children with severe symptoms with a potentially life changing drug administered by monthly – not daily – injection. Yes, the medication is expensive, but I would argue that the cost of future care for these children, if not managed as best as possible now, could likely be quite high.

s.22

Thank you for considering my request for the coverage of Canakinumab for other families that need it. I would ask that you schedule a meeting with David Porte of Cassie and Friends to discuss the matter further. He can be reached at his office at 604-732-7651 x 105, on his mobile number ^{s.22} or through his email at david@porte.ca

With thanks,

s.22

Barry, Brittany JR HLTH:EX

From: Tan, Dominic HLTH:EX
Sent: Thursday, January 4, 2018 5:29 PM
To: Bouma, Susan HLTH:EX; Lun, Eric HLTH:EX; Chong, Elaine HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX
Subject: RE: Canakinumab PLA

s.13,s.17

From: Bouma, Susan HLTH:EX
Sent: Thursday, January 4, 2018 5:25 PM
To: Tan, Dominic HLTH:EX; Lun, Eric HLTH:EX; Chong, Elaine HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX
Subject: RE: Canakinumab PLA

Interesting!

s.13,s.17

S

From: Tan, Dominic HLTH:EX
Sent: Thursday, January 4, 2018 1:23 PM
To: Lun, Eric HLTH:EX; Bouma, Susan HLTH:EX; Chong, Elaine HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX
Subject: FW: Canakinumab PLA

Hi,

s.13,s.17

I will just confirm receipt of the email from Geoff.

Dom

From: Squires, Geoffrey [<mailto:geoffrey.squires@novartis.com>]
Sent: Thursday, January 4, 2018 8:31 AM
To: Tan, Dominic HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; McLean, Michael
Subject: Canakinumab PLA

Hello Dom & Tijana, best of the new year.

s.22 and wanted to send you a quick note confirming our mid-December discussion.

s.13,s.17

Please don't hesitate to contact me at any time.

Kind regards,

Geoff Squires, BSP, RPh

Manager, Health Policy & Patient Access - British Columbia / Saskatchewan

Tel: +1 604 532-8735

Email: geoffrey.squires@novartis.com

Novartis Pharmaceuticals Canada Inc.

www.novartis.ca

Barry, Brittany JR HLTH:EX

From: Tan, Dominic HLTH:EX
Sent: Thursday, January 4, 2018 5:33 PM
To: 'Squires, Geoffrey'
Cc: Fazlagic, Tijana HLTH:EX; McLean, Michael
Subject: RE: Canakinumab PLA

Hi Geoff,

Thanks for the note. Will advise if we have any questions.

Dom

From: Squires, Geoffrey [<mailto:geoffrey.squires@novartis.com>]
Sent: Thursday, January 4, 2018 8:31 AM
To: Tan, Dominic HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; McLean, Michael
Subject: Canakinumab PLA

Hello Dom & Tijana, best of the new year.

s.22 and wanted to send you a quick note confirming our mid-December discussion.

s.13,s.17

Please don't hesitate to contact me at any time.

Kind regards,

Geoff Squires, BSP, RPh
Manager, Health Policy & Patient Access - British Columbia / Saskatchewan

Tel: +1 604 532-8735
Email: geoffrey.squires@novartis.com

Novartis Pharmaceuticals Canada Inc.

www.novartis.ca

Barry, Brittany JR HLTH:EX

From: Bouma, Susan HLTH:EX
Sent: Friday, January 12, 2018 11:29 AM
To: Tan, Dominic HLTH:EX; Lun, Eric HLTH:EX; Fazlagic, Tijana HLTH:EX; Rizzardo, Shirin HLTH:EX
Subject: RE: Canakinumab PLA

Thanks Dom!

From: Tan, Dominic HLTH:EX
Sent: Thursday, January 11, 2018 4:32 PM
To: Bouma, Susan HLTH:EX; Lun, Eric HLTH:EX; Fazlagic, Tijana HLTH:EX; Rizzardo, Shirin HLTH:EX
Subject: RE: Canakinumab PLA

s.13,s.16,s.17

Dom

From: Bouma, Susan HLTH:EX
Sent: Thursday, January 11, 2018 12:27 PM
To: Tan, Dominic HLTH:EX; Lun, Eric HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX
Subject: RE: Canakinumab PLA

I think so yes

From: Tan, Dominic HLTH:EX
Sent: Thursday, January 11, 2018 10:39 AM
To: Lun, Eric HLTH:EX; Bouma, Susan HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX
Subject: RE: Canakinumab PLA

s.13,s.16,s.17

In any event, we will need to send an email summarizing the matter and seek formal feedback.

s.13,s.16,s.17

Dom

From: Lun, Eric HLTH:EX
Sent: Wednesday, January 10, 2018 5:38 PM
To: Tan, Dominic HLTH:EX; Bouma, Susan HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX
Subject: Re: Canakinumab PLA

I think you have it except, s.13,s.17
s.13,s.17

, That may elicit more
interest.

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization
Pharmaceutical Services Division
BC Ministry of Health

From: Tan, Dominic HLTH:EX
Sent: Wednesday, January 10, 2018 14:47
To: Lun, Eric HLTH:EX; Bouma, Susan HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX
Subject: RE: Canakinumab PLA

I will ask for this to be added to tomorrow's agenda.

For my benefit, this is what I understand so far:
s.13,s.17

Please let me know if I have it right.

Thanks,
Dom

From: Lun, Eric HLTH:EX
Sent: Wednesday, January 10, 2018 11:35 AM
To: Bouma, Susan HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Tan, Dominic HLTH:EX
Subject: RE: Canakinumab PLA

Spoke to Dom about this and Dom (or I) will be raising it to see if there is interest to approach via pCPA.
Eric

From: Bouma, Susan HLTH:EX
Sent: Wednesday, January 10, 2018 11:29 AM
To: Lun, Eric HLTH:EX

Cc: Fazlagic, Tijana HLTH:EX
Subject: FW: Canakinumab PLA

Hi Eric!

Are you planning on bringing to PCPA table?

Thanks,
Sue

From: Tan, Dominic HLTH:EX
Sent: Wednesday, January 10, 2018 10:19 AM
To: Bouma, Susan HLTH:EX
Subject: FW: Canakinumab PLA

From: Squires, Geoffrey [<mailto:geoffrey.squires@novartis.com>]
Sent: Thursday, January 4, 2018 8:31 AM
To: Tan, Dominic HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; McLean, Michael
Subject: Canakinumab PLA

Hello Dom & Tijana, best of the new year.

s.22 and wanted to send you a quick note confirming our mid-December discussion.

s.13,s.17

Please don't hesitate to contact me at any time.

Kind regards,

Geoff Squires, BSP, RPh
Manager, Health Policy & Patient Access - British Columbia / Saskatchewan

Tel: +1 604 532-8735
Email: geoffrey.squires@novartis.com

Novartis Pharmaceuticals Canada Inc.

www.novartis.ca

Barry, Brittany JR HLTH:EX

From: Tan, Dominic HLTH:EX
Sent: Tuesday, January 16, 2018 12:50 PM
To: 'Lee, Sang Mi (MOHLTC)'; Srisombun, Anchalee (MOHLTC); 'adburke@ihis.org'; Ali, Imran (MOHLTC); 'Andrea.Laturnas@health.gov.sk.ca'; 'brcairns@gov.pe.ca'; 'carole.marcotte@msss.gouv.qc.ca'; Chan, Winnie (MOHLTC); Ingram, Chris HLTH:EX; XT:Ryan, Colleen HLTH:IN; 'daniel.mclean@canada.ca'; 'dominic.belanger@msss.gouv.qc.ca'; Chong, Elaine HLTH:EX; Lun, Eric HLTH:EX; 'Erika.Bell@gov.mb.ca'; 'Greg.Gandoke@gov.ab.ca'; 'JamieODea@gov.nl.ca'; 'Jeff.Onyskiw@gov.mb.ca'; 'jocelyn.milburn@gov.ab.ca'; 'karen.fortin@canada.ca'; 'Katherine.Scott@gnb.ca'; 'Kathleen.Coleman@novascotia.ca'; Uyeno, Kelly HLTH:EX; 'Kevin.Pothier@gnb.ca'; Kim, Andrew (MOHLTC); 'lara.grant@novascotia.ca'; XT:HLTH Jardine, Leanne; Lee, Simon (MOHLTC); McGrath, Mary (MOHLTC); 'Michelle.Glab@health.gov.sk.ca'; 'Nick.Doulias@health.gov.sk.ca'; XT:HLTH Clark, Patricia; Podkoscielny, Nessa (MOHLTC); 'Rachel.Cheruvallath@health.gov.sk.ca'; 'Sandra.Rees@gov.ab.ca'; 'scott.erwin@msss.gouv.qc.ca'; 'Sean.Eichendorf@gov.yk.ca'; Rizzardo, Shirin HLTH:EX; Sperber, Daniel (MOHLTC); 'stephanie.minnema@gov.ab.ca'; 'susan.pierce@canada.ca'; Fazlagic, Tijana HLTH:EX; 'Tina.LeClerc@gnb.ca'; 'tuan.dang@canada.ca'; Wong, Angie H (MOHLTC); Wong, Margaret S. (MOHLTC); 'yvan.gaudet@msss.gouv.qc.ca'
Subject: Ilaris for sJIA

Hi Folks,
s.13,s.16,s.17

Kindly advise.

Thanks,
Dom

CONFIDENTIALITY NOTICE: This information is directed in confidence solely to the person named above and may contain confidential and/or privileged material. This information may not otherwise be distributed, copied or disclosed. If you have received this e-mail in error, please notify the sender immediately via a return e-mail and destroy the original message. Thank you.

Barry, Brittany JR HLTH:EX

From: Pothier, Kevin (DH/MS) <Kevin.Pothier@gnb.ca>
Sent: Thursday, January 18, 2018 4:47 AM
To: Tan, Dominic HLTH:EX
Cc: 'Lee, Sang Mi (MOHLTC)'; Srisombun, Anchalee (MOHLTC); 'adburke@ihis.org'; Ali, Imran (MOHLTC); 'Andrea.Laturnas@health.gov.sk.ca'; 'brcairns@gov.pe.ca'; 'carole.marcotte@msss.gouv.qc.ca'; Chan, Winnie (MOHLTC); Ingram, Chris HLTH:EX; XT:Ryan, Colleen HLTH:IN; 'daniel.mclean@canada.ca'; 'dominic.belanger@msss.gouv.qc.ca'; Chong, Elaine HLTH:EX; Lun, Eric HLTH:EX; 'Erika.Bell@gov.mb.ca'; 'Greg.Gandoke@gov.ab.ca'; 'JamieODea@gov.nl.ca'; 'Jeff.Onyskiw@gov.mb.ca'; 'jocelyn.milburn@gov.ab.ca'; 'karen.fortin@canada.ca'; Scott, Katherine (DH/MS); 'Kathleen.Coleman@novascotia.ca'; Uyeno, Kelly HLTH:EX; Kim, Andrew (MOHLTC); 'lara.grant@novascotia.ca'; XT:HLTH Jardine, Leanne; Lee, Simon (MOHLTC); McGrath, Mary (MOHLTC); 'Michelle.Glab@health.gov.sk.ca'; 'Nick.Doulis@health.gov.sk.ca'; XT:HLTH Clark, Patricia; Podkoscielny, Nessa (MOHLTC); 'Rachel.Cheruvallath@health.gov.sk.ca'; 'Sandra.Rees@gov.ab.ca'; 'scott.erwin@msss.gouv.qc.ca'; 'Sean.Eichendorf@gov.yk.ca'; Rizzardo, Shirin HLTH:EX; Sperber, Daniel (MOHLTC); 'stephanie.minnema@gov.ab.ca'; 'susan.pierce@canada.ca'; Fazlagic, Tijana HLTH:EX; LeClerc, Tina (DH/MS); 'tuan.dang@canada.ca'; Wong, Angie H (MOHLTC); Wong, Margaret S. (MOHLTC); 'yvan.gaudet@msss.gouv.qc.ca'; Pothier, Kevin (DH/MS)
Subject: RE: Ilaris for sJIA

Hi Dom,

Please see NBs response below in RED.

Kevin

From: Tan, Dominic HLTH:EX [<mailto:Dominic.Tan@gov.bc.ca>]
Sent: January-16-18 4:50 PM
To: 'Lee, Sang Mi (MOHLTC)'; Srisombun, Anchalee (MOHLTC); 'adburke@ihis.org'; Ali, Imran (MOHLTC); 'Andrea.Laturnas@health.gov.sk.ca'; 'brcairns@gov.pe.ca'; 'carole.marcotte@msss.gouv.qc.ca'; Chan, Winnie (MOHLTC); Ingram, Chris HLTH:EX; XT:Ryan, Colleen HLTH:IN; 'daniel.mclean@canada.ca'; 'dominic.belanger@msss.gouv.qc.ca'; Chong, Elaine HLTH:EX; Lun, Eric HLTH:EX; 'Erika.Bell@gov.mb.ca'; 'Greg.Gandoke@gov.ab.ca'; 'JamieODea@gov.nl.ca'; 'Jeff.Onyskiw@gov.mb.ca'; 'jocelyn.milburn@gov.ab.ca'; 'karen.fortin@canada.ca'; Scott, Katherine (DH/MS); 'Kathleen.Coleman@novascotia.ca'; Uyeno, Kelly HLTH:EX; Pothier, Kevin (DH/MS); Kim, Andrew (MOHLTC); 'lara.grant@novascotia.ca'; Jardine, Leanne (DH/MS); Lee, Simon (MOHLTC); McGrath, Mary (MOHLTC); 'Michelle.Glab@health.gov.sk.ca'; 'Nick.Doulis@health.gov.sk.ca'; XT:HLTH Clark, Patricia; Podkoscielny, Nessa (MOHLTC); 'Rachel.Cheruvallath@health.gov.sk.ca'; 'Sandra.Rees@gov.ab.ca'; 'scott.erwin@msss.gouv.qc.ca'; 'Sean.Eichendorf@gov.yk.ca'; Rizzardo, Shirin HLTH:EX; Sperber, Daniel (MOHLTC); 'stephanie.minnema@gov.ab.ca'; 'susan.pierce@canada.ca'; Fazlagic, Tijana HLTH:EX; LeClerc, Tina (DH/MS); 'tuan.dang@canada.ca'; Wong, Angie H (MOHLTC); Wong, Margaret S. (MOHLTC); 'yvan.gaudet@msss.gouv.qc.ca'
Subject: Ilaris for sJIA

Hi Folks,

Kindly advise.

Thanks,
Dom

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Traverse, Chantal HLTH:EX

From: Stevens, Sandy HLTH:EX
Sent: Friday, December 8, 2017 4:30 PM
To: McClymont, Brenda HLTH:EX; HLTH Corporate Operations HLTH:EX
Cc: Scott, Pam HLTH:EX; Stevens, Sandy HLTH:EX; Bouma, Susan HLTH:EX; Traverse, Chantal HLTH:EX; Raine, Andrea L HLTH:EX; Maglanque, Joyce HLTH:EX
Subject: URGENT FW: ASAP s.22 - CONSENT FORM --
RE: MEDIA REQUEST

Importance: High

Hi Brenda:

As of Friday at 4:30 pm this has not come down from Corporate Operations.....therefore I am assuming it will be entered after I left tonight, and will have to be assigned thereafter.

Thanks
Sandy

From: Peluso, Jenna HLTH:EX
Sent: Friday, December 8, 2017 4:23 PM
To: McClymont, Brenda HLTH:EX; Stevens, Sandy HLTH:EX
Cc: Scott, Pam HLTH:EX; Bouma, Susan HLTH:EX
Subject: ASAP s.22 - CONSENT FORM -- RE: MEDIA REQUEST
Importance: High

Hi Brenda and Sandy,

FYI - Sue and I just spoke with Jordan regarding the email below- Sue is calling s.22 now as instructed by the Minister's office.

Once this is formally assigned to us (is has not been yet) Please add the Telephone response template for Sue to document the conversation and for us to formally respond next week.

Thank you,
Jenna

Jenna Peluso
Program Coordinator
Business Continuity Coordinator, SharePoint Divisional Site Administrator
Assistant Deputy Minister's Office
Pharmaceutical Services Division
Ministry of Health

1515 Blanshard St | PO BOX 9652 STN PROV GOVT | Victoria BC | V8W 9P4
(250) 952-1169 | Jenna.Peluso@gov.bc.ca

From: Bouma, Susan HLTH:EX
Sent: Friday, December 8, 2017 4:12 PM
To: Will, Jordan HLTH:EX; Peluso, Jenna HLTH:EX
Cc: Burnham, Lindsey HLTH:EX; Fougere, Brianna HLTH:EX
Subject: RE: ASAP s.22

- CONSENT FORM -- RE: MEDIA REQUEST

s.22

From: Will, Jordan HLTH:EX
Sent: Friday, December 8, 2017 3:38 PM
To: Peluso, Jenna HLTH:EX; Bouma, Susan HLTH:EX
Cc: Burnham, Lindsey HLTH:EX; Fougere, Brianna HLTH:EX
Subject: FW: ASAP s.22
Importance: High

CONSENT FORM -- RE: MEDIA REQUEST

Good afternoon Sue and Jenna,

This has just been received from the Minister's Office and the formal assignment will be coming to you shortly. I wanted to reach out directly as s.22 The MO is looking for a connection to be made with s.22 today and a response for MO review to follow shortly (ie early next week). Are you able to have someone on your team connect with s.22 today based on the info that we have and let them know that we are addressing the situation and will have a more formal response coming to them next week?

Let me know if you would like to discuss further or you have any concerns.

Thank you,

JORDAN WILL
Director, Executive Operations
Office of the Deputy Minister
Ministry of Health

P: 250.952.1908 | Jordan.Will@gov.bc.ca

From: Burnham, Lindsey HLTH:EX
Sent: Friday, December 8, 2017 3:23 PM
To: HLTH Corporate Operations HLTH:EX
Cc: Will, Jordan HLTH:EX; Andrachuk, Andrea HLTH:EX
Subject: FW: ASAP case work FW: s.22
REQUEST - SOOKE MIRROR NEWS -- Please please read. Thank you
Importance: High

- CONSENT FORM -- RE: MEDIA

Hi team,

Please see case information and instruction from Cassandra below.

Let me know if anything further is required or if you have any questions.

Thank you,

Lindsey Burnham
Ministerial Liaison | Executive Operations |

From: Dycke, Kassandra HLTH:EX
Sent: Friday, December 8, 2017 2:32 PM
To: Burnham, Lindsey HLTH:EX
Subject: ASAP case work FW: ^{s.22}
SOOKE MIRROR NEWS -- Please please read. Thank you
Importance: High

- CONSENT FORM -- RE: MEDIA REQUEST -

Hi Lindsey,

Please forward this on as case work, asap. This is a ^{s.22} and urgent for ^{s.22} I would appreciate if the Ministry could place a call to ^{s.22} as a top priority, to gather additional information that may be needed, and assures ^{s.22} this is receiving our soonest attention. Could I ask for a direct response to the constituent, but provided to me to review and approve before it is delivered?

Thanks so much.
Kass

Kassandra Dycke
Ministerial Assistant to
Hon. Adrian Dix, Minister of Health
Room 337 | Parliament Buildings, Victoria, BC | V8W 9V1
Office 250-953-3584 | Cell ^{s.17}
kassandra.dycke@gov.bc.ca

From: Mitchell-Starkey, Maureen [<mailto:Maureen.Mitchell-Starkey@leg.bc.ca>]
Sent: Friday, December 8, 2017 1:28 PM
To: McConnell, Sheena PREM:EX; Dycke, Kassandra HLTH:EX; Holmwood, Jen PREM:EX
Cc: Horgan.MLA. John LASS:EX; Frederiksen, Hans LASS:EX; Osborn, Lynn LASS:EX; Nash, Amber PREM:EX
Subject: ^{s.22} - CONSENT FORM -- RE: MEDIA REQUEST - SOOKE MIRROR
NEWS -- Please please read. Thank you

Amber -- as requested I have attached ^{s.22} consent form for ^{s.22}

Contact Information:

^{s.22}

Maureen Mitchell-Starkey | Constituency Assistant to Honourable John Horgan, MLA, Langford-Juan de Fuca
#122 - 2806 Jacklin Road Victoria BC V9B 5A4 | P: 250-391-2801 | F: 250-391-2804

Page 004 to/à Page 014

Withheld pursuant to/removed as

s.22

Traverse, Chantal HLTH:EX

From: Bouma, Susan HLTH:EX
Sent: Monday, December 11, 2017 5:59 PM
To: Moneo, Mitch HLTH:EX
Cc: Lun, Eric HLTH:EX
Subject: RE: sJIA

Hi Mitch:

That is correct, s.22
s.22

- cost for canakinumab ranges from \$192,000/year (current for s.22 to \$768,000/year for older heavier patients.
- comparators (tocilizumab and anakinra) are approximately \$20,000/year.
- canakinumab can be given subcutaneously and is given less often (every 4 weeks) vs tocilizumab intravenously (every two weeks) and anakinra subcutaneous (daily).
- jurisdictional scan shows:

s.13,s.16

We do need to get back to s.22 with our decision in the next few days.

e-Approve with the TRs is coming your way.
Sue

From: Moneo, Mitch HLTH:EX
Sent: Monday, December 11, 2017 4:36 PM
To: Bouma, Susan HLTH:EX
Cc: Lun, Eric HLTH:EX
Subject: SJIA

Hi Sue,

I see I have a briefing with the DM on s.22 first this tomorrow morning.

You mentioned that we were s.22 Can you please prove me with details so I
am prepared for my 8:30 am meeting.

Thanks

Mitch Moneo
Pharmaceutical Services Division
☎ 250 952-1464



Telephone Response Log

Assignment Due Date: December 12, 2017

Cliff #: 1099464

Date / Time of Call: December 11, 2017 / 11:00 am – 11:05 am

Name & Number of Person Contacted: s.22

ISSUE / REQUEST: Inquiry regarding the Ministry of Health funding for canakinumab for s.22

BACKGROUND:

- Canakinumab is a biologic medication that is indicated for systemic juvenile idiopathic arthritis (sJIA). Cost is approximately \$16,000 per 150 mg dose; doses for older/ heavier patients can approach and possibly even exceed 600 mg every four weeks. It is a subcutaneous injection. The potential annual cost for 150 mg dosage is about \$192,000 per year and \$768,000 per year for the 600 mg dosage every four weeks.
- Tocilizumab is administered every two weeks as an intravenous infusion. It has the Health Canada indication for sJIA and is eligible for PharmaCare coverage for this indication. Tociliaumab costs much less than canakinumab at usually less than \$20,000 per year.
- Prior to tocilizumab's entry into the market, anakinra was used very commonly off-label to treat sJIA. This medication is still commonly approved by British Columbia PharmaCare for this indication on an exceptional basis. It is a once daily subcutaneous injection, and cost is much less than canakinumab (anakinra is approximately \$20,000 per year).

DETAILS OF CONVERSATION:

s.22

Follow-up correspondence requested? ^{s.22}

Name of staff member who contacted the individual: Jason Gordon

Telephone: 250 952-2975

Program area: Special Authority
Drug Intelligence and Optimization
Pharmaceuticals Services Division

Date: December 11, 2017

December 12, 2017

By e-mail: mary.polak.mla@leg.bc.ca
rich.coleman.mla@leg.bc.ca
premier@gov.bc.ca
adrian.dix.MLA@leg.bc.ca

Cc:

The Honourable Premier John Horgan
P.O. Box 9041 Stn Prov Govt
Victoria, BC V8W 9E1

The Honourable Minister Adrian Dix
Room 337 Parliament Buildings
Victoria, BC V8V 1X4

Dear Mary Polak, Rich Coleman, Premier Horgan and Minister Dix:

Re: Coverage of Canakinumab

(I am a constituent of Abbotsford south, Darryl Plecas riding, and I am unaware who is currently the MLA for our riding)

s.22

s.22 Cassie & Friends Society - a registered Canadian charity based in Vancouver - and I'm writing you, to provide information on Juvenile Idiopathic Arthritis (JIA) in BC and to bring your attention to this issue. The BC government could significantly improve the treatment for children living with a rare type of JIA (systemic juvenile idiopathic arthritis or "SJIA") by reimbursing canakinumab (Ilaris) for the small number of children who need it.

JIA affects approximately 24,000 children and teens in Canada, or 3 in every 1,000 children and teens, making it one of the most common causes of chronic disability in children. Ten to 20 percent of children with JIA have Systemic Juvenile Idiopathic Arthritis (SJIA), a severe and potentially life-threatening form of the disease more challenging to diagnose and treat than other types of JIA. JIA and SJIA can be devastating and come with high financial, family and societal burdens. Approximately 60% of children will have active disease into adulthood.

s.22

There is no cure for JIA. Today, there are treatments available that can prevent the long-term damage and disability caused by JIA and help children lead a normal life. New biologic targeted treatments, have revolutionized the care and outcomes for many children with JIA. Today, the "new normal" for children living with JIA means thriving in the classroom and playing sports outdoors, rather than being housebound in a wheelchair, completely isolated from all the things that make up a person's childhood.

Evidence from leading researchers at the Pediatric Rheumatology Division at BC Children's Hospital clearly demonstrates that **early diagnosis and urgent treatment** of JIA in children can profoundly improve in even the most severe cases. We commend the BC government for recognizing this and being leaders in providing reimbursement access to some of the biologic medications indicated to treat JIA.

However, there is an urgent need for the BC government to do more for the small number of children with severe SJIA who need reimbursement access to canakinumab, currently not covered by BC PharmaCare.

Canakinumab is a biologic medication that targets the specific immune dysfunction we now know is causing the severe symptoms of SJIA. An international treatment trial of canakinumab for children with SJIA showed it to be extremely effective in stopping disease symptoms, and allowing rapid discontinuation of other medications like steroids which result in intolerable side effects to kids. The other major benefit of this medication is that it is given by a once monthly injection, which is easy to tolerate in the young children who need it, some of whom are as young as 2 years old. The comparator medication for SJIA requires a daily, excruciatingly painful injection which can be extremely stressful, or even impossible for families of young children to administer. s.22
s.22

We estimate there are relatively few children in BC that will require Canakinumab, as most children with SJIA respond to other treatments. However, for these vulnerable and ill children, canakinumab is their only hope to avoid the progression of their disabling symptoms.

Canakinumab has been approved by Health Canada, but currently is not covered by BC Pharmacare. This medication is available on application for children with SJIA in Ontario and Nova Scotia, based on entry criteria designed in collaboration with pediatric

rheumatologists. Coverage for this medication through extended health insurance is variable, and therefore sets up a situation in BC that disadvantages children whose families do not have extended insurance, resulting in poor quality care and bad patient outcomes.

s.22

Cassie & Friends and our clinical experts would like to meet and work with you to develop criteria for BC PharmaCare reimbursement coverage for the children who need it. No child in BC should be left behind by our healthcare system, and sadly, that is precisely what is happening in our community.

I look forward to hearing your feedback on this important issue. In the meantime, please don't hesitate to contact me by email at s.22 or by phone @

s.22

Sincerely,

s.22

Juvenile Idiopathic Arthritis (JIA) Backgrounder

Who is Cassie & Friends Society

Cassie & Friends works to transform the lives of kids and families affected by JIA and other childhood rheumatic diseases. We offer support programs for kids and families, including Canada's largest annual JIA patient and family gathering. Additionally, our community of families, healthcare professionals and other friends have volunteered more than 25,000 hours of service to help kids and families living with JIA. Since 2007, this organization has raised over \$1.5 million dollars to fund research, pediatric rheumatology programs, equipment, support services and educational events to kids and families with JA and related rheumatic diseases.

How is arthritis diagnosed in children?

Arthritis is diagnosed by examination of the child by a doctor who has specialized training (or experience) in childhood rheumatic diseases. Preliminary evaluation should be by the family doctor or pediatrician, but the final diagnosis is ideally made by a pediatric rheumatologist. There are no blood tests or x-rays to confirm a diagnosis but these tests may be useful to determine the type of arthritis, to assess the severity, or to identify complications.

What is the usual course of JIA?

This is very difficult to predict at the outset, and to some extent, it depends on the type of JIA. In a small number of children, the disease may last as little as several months to a year and disappear forever. Most children, however, have an up-and-down course with "flares" and "remissions" for many years with about half of them continuing to have problems into adulthood. While there is no cure for JIA, current available therapy often prevents long-term damage and disability that may be left by arthritis even after it has gone.

Is childhood arthritis treated the same as adult-type arthritis?

Children with arthritis are not just kids with an adult disease. Although the drugs and therapies used to treat children are similar, the intensity of treatment and the frequency of follow-ups need to be much greater.

Unlike for adults with arthritis for example, physical growth may be stunted, children may grow one leg longer than the other, or one hand or foot may be smaller. Some children with arthritis can also have associated eye inflammation that can lead to blindness. These changes may be irreversible if there is a delay, or poor follow-up, in treatment. The impact of any chronic illness on psychological development, especially during adolescence, should not be underestimated as it can have lifelong recreational, educational, and career implications.

What is the treatment guideline for SJIA?

Until recently, however, few treatment alternatives to corticosteroids existed for kids with SJIA. But over the past few years, Health Canada has approved medications that target specific inflammatory proteins, including interleukin-1 (IL-1) and interleukin-6 (IL-6), which

are overactive in the disease. These drugs, known as biologics, were once used only after other medications had been tried and failed. But because they can cause a dramatic improvement in some children with SJIA, some physicians now use biologics as a first-line therapy, avoiding corticosteroids and their side effects completely.

Traverse, Chantal HLTH:EX

From: McClymont, Brenda HLTH:EX
Sent: Tuesday, December 12, 2017 3:42 PM
To: Bouma, Susan HLTH:EX
Cc: Stevens, Sandy HLTH:EX
Subject: RE: SJIA Issue

What is the ID # in eApproval.

From: Bouma, Susan HLTH:EX
Sent: Tuesday, December 12, 2017 3:41 PM
To: McClymont, Brenda HLTH:EX
Cc: Stevens, Sandy HLTH:EX
Subject: RE: SJIA Issue

Have not seen a number on it...

From: McClymont, Brenda HLTH:EX
Sent: Tuesday, December 12, 2017 3:33 PM
To: Bouma, Susan HLTH:EX
Cc: Stevens, Sandy HLTH:EX
Subject: RE: SJIA Issue

Hi Sue, do you know the Cliff number of the IN?

From: Bouma, Susan HLTH:EX
Sent: Tuesday, December 12, 2017 2:19 PM
To: Scott, Pam HLTH:EX
Cc: Moneo, Mitch HLTH:EX; Lun, Eric HLTH:EX; McClymont, Brenda HLTH:EX; Stevens, Sandy HLTH:EX; El Agab, Charlotte S HLTH:EX; Will, Jordan HLTH:EX
Subject: Re: SJIA Issue

Yes, going with that the s.22
and Eric right now.

some bullets already provided and IN pending approval is with me

Sue

Sent from my iPhone

On Dec 12, 2017, at 2:14 PM, Scott, Pam HLTH:EX <Pam.Scott@gov.bc.ca> wrote:

Sue. Are you able to address

Sent from my iPhone

Begin forwarded message:

From: "Will, Jordan HLTH:EX" <Jordan.Will@gov.bc.ca>
Date: December 12, 2017 at 2:00:51 PM PST
To: "Scott, Pam HLTH:EX" <Pam.Scott@gov.bc.ca>

Cc: "El Agab, Charlotte S HLTH:EX" <Charlotte.Elagab@gov.bc.ca>,
"McClymont, Brenda HLTH:EX" <brenda.mcclymont@gov.bc.ca>, "Fougere,
Brianna HLTH:EX" <Brianna.Fougere@gov.bc.ca>
Subject: RE: SJIA Issue

Hi Pam,

Jasmyn in the MO has requested a quick update on this case and I understand there have been some recent discussions. Are you able to acquire a few bullets or information that could be provided to update the MO on the status of the case?

Let me know if you'd like to discuss.

Thank you,

JORDAN WILL
Director, Executive Operations
Office of the Deputy Minister
Ministry of Health

P: 250.952.1908 | Jordan.Will@gov.bc.ca

From: Will, Jordan HLTH:EX
Sent: Monday, December 11, 2017 10:00 AM
To: Feulgen, Sabine HLTH:EX; Moneo, Mitch HLTH:EX
Cc: Stearn, Anne HLTH:EX; Fougere, Brianna HLTH:EX; Anderson, Kristy GCPE:EX; Scott, Pam HLTH:EX
Subject: SJIA Issue

Good morning,

As we discussed, here is the summary of emails and information we have received so far on this case of s.22
s.22

s.22 and provided a brief email summary that I've included below. Jasmyn has requested an update today or tomorrow on the case as well as some questions about other jurisdictions' coverage etc.

Two MA's, Jasmyn and Cassandra, have been involved thus far. We'll work to make sure they work through the process and we don't have overlapping requests.

Description	Attachment
Initial Incoming email from s.22 to her MLA case from friday >> John Horgan	<< Message: FW: in relation to the s.22 to her MLA case from friday >>
Short summary of	<< Message: RE: ASAP s.22

Sue's conversation with s.22 s.22
 s.22 - CONSENT FORM -- RE: MEDIA REQUEST >>
 << Message: FW: ASAP case work FW: s.22
 Kristy response to s.22 - CONSENT
 Jasmyn's email to s.22 FORM -- RE: MEDIA REQUEST -
 Eric SOOKE MIRROR NEWS -- Please
 please read. Thank you >>

Let me know if there's anything else I can provide at this time.
 Thank you,

JORDAN WILL
 Director, Executive Operations
 Office of the Deputy Minister
 Ministry of Health

P: 250.952.1908 | Jordan.Will@gov.bc.ca

Page 027

Withheld pursuant to/removed as

s.22

Traverse, Chantal HLTH:EX

From: s.22
Sent: Wednesday, December 13, 2017 6:50 PM
To: Minister, HLTH HLTH:EX
Subject: s.22

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Assign

HLTH MO to PSD – xref 1099464 and 1099621 – dd

Sent from my iPhoneHello,

I am writing in to show my support for s.22

s.22

s.22

s.22

s.22

s.22

On the government website it states, and I quote

“ Fairpharmacare also ensures that B.C. residents, REGARDLESS of income, are protected from catastrophic drug costs. “

(Emphasis mine)

So how is it that s.22

Further to this, the drug that could help s.22 is only sold in one dosage! s.22
s.22

I expect an email and some answers in regards to this matter.

Thank you for your time,
s.22

Traverse, Chantal HLTH:EX

From: Dix.MLA, Adrian <Adrian.Dix.MLA@leg.bc.ca>
Sent: Wednesday, December 13, 2017 9:55 AM
To: Minister, HLTH HLTH:EX
Subject: FW: Letter to Premier and Minister of Health regarding Canakinumab
Attachments: 2017 12 12 LT RK to Premier Horgan and Minister Dix re Canakinumab (00416240xC6E53).pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: PRIORITY, Assign

HLTH MO to PSD – dd

From: s.22
Sent: Tuesday, December 12, 2017 9:43 PM
To: premier@gov.bc.ca; Dix.MLA, Adrian
Cc: Thornthwaite.MLA, Jane
Subject: Letter to Premier and Minister of Health regarding Canakinumab

Premier Horgan and Minister Dix - Please find attached my letter in relation to the coverage of Canakinumab. Thank you.



Telephone Response Log

Assignment Due Date: December 14, 2017

Cliff #: 1099621

Date / Time of Call: December 13, 2017 / 9:20 am – 9:25 am

Name & Number of Person Contacted: s.22

ISSUE / REQUEST: s.22 would like to know the status of Ministry of Health decision is regarding the approval of this drug for s.22

BACKGROUND:

- s.22 and the desire to have canakinumab funded.

DETAILS OF CONVERSATION:

s.22

Follow up correspondence requested? No

Name of staff member who contacted the individual: Jason Gordon, Pharmacist Consultant

Telephone: 250 952-2975

Program area: Special Authority
Drug Intelligence and Optimization
Pharmaceuticals Services Division

Date: December 13, 2017

Traverse, Chantal HLTH:EX

From: Dix.MLA, Adrian <Adrian.Dix.MLA@leg.bc.ca>
Sent: Thursday, December 14, 2017 9:25 AM
To: Minister, HLTH HLTH:EX
Subject: 1099967 s.22 Canakinumab

Categories: Suzanne, Assign

HLTH MO to PSD - xref 1099464 - dd

-----Original Message-----

From s.22

Sent: Thursday, December 14, 2017 8:02 AM

To: Dix.MLA, Adrian <Adrian.Dix.MLA@leg.bc.ca>

Cc: john.horgon.mla@leg.bc.ca

Subject: Landen

Dear Adrian,

s.22

happen to make this happen?!!

s.22

What if this was your child? What needs to

Traverse, Chantal HLTH:EX

From: Scott, Pam HLTH:EX
Sent: Monday, December 18, 2017 10:13 AM
To: Bouma, Susan HLTH:EX
Subject: URGENT: 1099464 - ASA s.22

Importance: High

Hi Sue,

The Minister's office has asked that you call s.22 asap as the Minister will be talking to media in an hour.

Anne indicated that they just want you to concentrate on the clinician piece (below) and to say that the Minister's office will be emailing s.22 shortly.

s.13,s.22

Begin forwarded message:

From: "Stearn, Anne HLTH:EX" <Anne.Stearn@gov.bc.ca>
To: "Bouma, Susan HLTH:EX" <Susan.Bouma@gov.bc.ca>, "Will, Jordan HLTH:EX" <Jordan.Will@gov.bc.ca>
Cc: "Peluso, Jenna HLTH:EX" <Jenna.Peluso@gov.bc.ca>, "Traverse, Chantal HLTH:EX" <Chantal.Traverse@gov.bc.ca>, "Andrachuk, Andrea HLTH:EX" <Andrea.Andrachuk@gov.bc.ca>
Subject: RE: 1099464 - ASA s.22

Hi Sue – Jas from the Minister's office just called and asked for an update on the call this morning to s.22 She's noted that the minister will be talking to the media in an hour so needs an update on how the call went in the next few minutes

Anne Stearn

Director, Office of the Deputy Minister
5th Floor - 1515 Blanshard Street, Victoria BC V8W 3C8
Phone (250) 952-3572 / e-mail: anne.stearn@gov.bc.ca

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From: Bouma, Susan HLTH:EX
Sent: Friday, December 15, 2017 4:49 PM
To: Will, Jordan HLTH:EX
Cc: Peluso, Jenna HLTH:EX; Stearn, Anne HLTH:EX; Traverse, Chantal HLTH:EX
Subject: RE: 1099464 - ASA s.22

I will call on Monday morning. Thanks for the looping.

S

From: Will, Jordan HLTH:EX
Sent: Friday, December 15, 2017 4:46 PM
To: Bouma, Susan HLTH:EX
Cc: Peluso, Jenna HLTH:EX; Stearn, Anne HLTH:EX
Subject: RE: 1099464 - ASA s.22

Hi Sue,

Just to close the loop, I made our case but they are still wanting the call Monday morning; the email delivery is tbd so we can't rely on that happening Monday morning.

Apologies. Let me know if you would like to discuss Monday morning again before you call

Thank you,

JORDAN WILL
Director, Executive Operations
Office of the Deputy Minister
Ministry of Health

P: 250.952.1908 | Jordan.Will@gov.bc.ca

From: Bouma, Susan HLTH:EX
Sent: Friday, December 15, 2017 2:40 PM
To: Will, Jordan HLTH:EX; Scott, Pam HLTH:EX; Peluso, Jenna HLTH:EX
Cc: McClymont, Brenda HLTH:EX; Stearn, Anne HLTH:EX; Fougere, Brianna HLTH:EX; HLTH Corporate Operations HLTH:EX; Stevens, Sandy HLTH:EX; Burnham, Lindsey HLTH:EX; Andrachuk, Andrea HLTH:EX; Moneo, Mitch HLTH:EX; Lun, Eric HLTH:EX
Subject: RE: 1099464 - ASA s.22

Hi!

Did our response not go out? I committed to the response going out early this week and it should have gone. Are you saying s.2 has not seen this yet?

Can you elaborate on the technical details that are to be changed? This information below would be how we need to consider things going forward and is a hint that other options need to be explored.

If I am to call ^{s.2} again, I would appreciate having clearer direction on what exactly to say. Especially if s.22 has not seen this response yet.

Thanks,
Sue

From: Will, Jordan HLTH:EX

Sent: Friday, December 15, 2017 2:22 PM

To: Scott, Pam HLTH:EX; Peluso, Jenna HLTH:EX

Cc: McClymont, Brenda HLTH:EX; Bouma, Susan HLTH:EX; Stearn, Anne HLTH:EX; Fougere, Brianna HLTH:EX; HLTH Corporate Operations HLTH:EX; Stevens, Sandy HLTH:EX; Burnham, Lindsey HLTH:EX; Andrachuk, Andrea HLTH:EX; Moneo, Mitch HLTH:EX; Lun, Eric HLTH:EX

Subject: FW: 1099464 - ASA s.22

Importance: High

Good afternoon Jenna,

I have just been in touch with the Minister's Office who has now requested further action on this file. On instruction from the PO after receiving the attached email (yellow envelope), the MO has requested that we reach out to s.22 once again, this time with a focus on the following paragraph from our draft email s.22 Email Response.docx) attached:

s.13,s.22

Please let me know if there are any concerns with this approach. Otherwise, if I can have a quick update once the call is made, it would be very much appreciated.

Thank you,

JORDAN WILL
Director, Executive Operations
Office of the Deputy Minister
Ministry of Health

P: 250.952.1908 | Jordan.Will@gov.bc.ca

From: HLTH Corporate Operations HLTH:EX

Sent: Thursday, December 14, 2017 10:42 AM

To: Dycke, Kassandra HLTH:EX; Singh, Jasmyn HLTH:EX

Cc: Will, Jordan HLTH:EX; HLTH Corporate Operations HLTH:EX; Burnham, Lindsey HLTH:EX; Andrachuk, Andrea HLTH:EX; Fougere, Brianna HLTH:EX; Stearn, Anne HLTH:EX

Subject: 1099464 - ASA^{s.22}

- CONSENT FORM -- RE: MEDIA

REQUEST - SOOKE MIRROR NEWS -- Please please read. Thank you

Importance: High

As promised below, attached is the draft email response for your review, approved by Mitch Moneo. Please let me know when this is approved for program staff to send.

Thanks so much,

Kathy Simonson

Documents Lead / Corporate Operations / DMO / Ministry of Health
5-3 1515 Blanshard St. Victoria BC V8W 3C8
Telephone 250 952-0998

kathy.simonson@gov.bc.ca

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From: HLTH Corporate Operations HLTH:EX

Sent: Thursday, December 14, 2017 10:11 AM

To: Dycke, Kassandra HLTH:EX

Cc: Will, Jordan HLTH:EX; HLTH Corporate Operations HLTH:EX; Burnham, Lindsey HLTH:EX; Andrachuk, Andrea HLTH:EX; Fougere, Brianna HLTH:EX; Stearn, Anne HLTH:EX

Subject: 1099464 - ASA^{s.22}

- CONSENT FORM -- RE: MEDIA

REQUEST - SOOKE MIRROR NEWS -- Please please read. Thank you

Importance: High

Further to your request below, Pharmaceutical Services Division has asked that we forward the attached telephone response summary documents as a top priority update on the case. Mitch Moneo, ADM has approved.

The email response requested is currently going through revisions requested by the ADM, but will be going through approvals shortly. We will send for your review once received.

Thanks so much,

Kathy Simonson

Documents Lead / Corporate Operations / DMO / Ministry of Health
5-3 1515 Blanshard St. Victoria BC V8W 3C8
Telephone 250 952-0998

kathy.simonson@gov.bc.ca

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From: Dycke, Kassandra HLTH:EX

Sent: Friday, December 8, 2017 2:32 PM

To: Burnham, Lindsey HLTH:EX

Subject: ASAP case work FW:^{s.22}

- CONSENT FORM -- RE:

MEDIA REQUEST - SOOKE MIRROR NEWS -- Please please read. Thank you

Importance: High

Hi Lindsey,

Please forward this on as case work, asap. s.22 and urgent for s.22 I would appreciate if the Ministry could place a call to s.22 as a top priority, to gather additional information that may be needed, and assure s.22 this is receiving our soonest attention. Could I ask for a direct response to the constituent, but provided to me to review and approve before it is delivered?

Thanks so much.

Kass

Kassandra Dycke

Ministerial Assistant to

Hon. Adrian Dix, Minister of Health

Room 337 | Parliament Buildings, Victoria, BC | V8W 9V1

Office 250-953-3584 | Cell s.17

kassandra.dycke@gov.bc.ca

From: Mitchell-Starkey, Maureen [<mailto:Maureen.Mitchell-Starkey@leg.bc.ca>]

Sent: Friday, December 8, 2017 1:28 PM

To: McConnell, Sheena PREM:EX; Dycke, Kassandra HLTH:EX; Holmwood, Jen PREM:EX

Cc: Horgan.MLA, John LASS:EX; Frederiksen, Hans LASS:EX; Osborn, Lynn LASS:EX; Nash, Amber PREM:EX

Subject: s.22

- CONSENT FORM -- RE: MEDIA REQUEST -

SOOKE MIRROR NEWS -- Please please read. Thank you

Amber -- as requested I have attached s.22 consent form for s.22

Contact Information:

s.22

Maureen Mitchell-Starkey | Constituency Assistant to Honourable John Horgan, MLA, Langford-Juan de Fuca

#122 - 2806 Jacklin Road Victoria BC V9B 5A4 | P: 250-391-2801 | F: 250-391-2804

From: s.22

Sent: December 7, 2017 10:26 PM

To: Horgan.MLA, John <John.Horgan.MLA@leg.bc.ca>

Subject: Please please read. Thank you

Dear John Horgan,

s.22

Page 037 to/à Page 039

Withheld pursuant to/removed as

s.22

Traverse, Chantal HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Monday, December 18, 2017 1:00 PM
To: Singh, Jasmyn HLTH:EX; Bouma, Susan HLTH:EX
Subject: RE: Direction Required: 1099464 - ASA s.22

Jasmyn and Sue:

Spoke to Cassandra. She will advise the Premier's CA to advise that s.22

s.22 However, if needed, s.22 can reach out to Sue Bouma again. For this, I have provided Cassandra Sue's assistant's phone # of 250-952-1090 should s.22 want to speak to someone at the Ministry. A written response is still expected later.

Spoke to Sue. She will connect with Dr. within the hour to review the circumstances and drug options that PharmaCare is willing to fund, and more importantly, hopefully come up with a mutually agreed upon approach. Sue will report back once she connects.

Thanks,

Eric

-----Original Message-----

From: Singh, Jasmyn HLTH:EX
Sent: Monday, December 18, 2017 12:35 PM
To: Lun, Eric HLTH:EX
Subject: RE: Direction Required: 1099464 - ASA s.22

Thanks Eric

Kassandra's digits - 250-953-3584. If you can connect with her, as she is working with the Premiers CA right now. Its been conveyed already that clinicians make the decision of when to pursue one of the many alternatives available for s.22 not MLAs.

-----Original Message-----

From: Lun, Eric HLTH:EX
Sent: Monday, December 18, 2017 12:32 PM
To: Singh, Jasmyn HLTH:EX
Subject: RE: Direction Required: 1099464 - ASA s.22

Jasmyn - Sue will be calling the MD to relay the information and will report back now.
Eric

-----Original Message-----

From: Lun, Eric HLTH:EX
Sent: Monday, December 18, 2017 12:23 PM
To: Singh, Jasmyn HLTH:EX
Subject: FW: Direction Required: 1099464 - ASA s.22

-----Original Message-----

From: Bouma, Susan HLTH:EX
Sent: Monday, December 18, 2017 12:13 PM
To: Lun, Eric HLTH:EX
Subject: FW: Direction Required: 1099464 - ASA l s.22

-----Original Message-----

From: Bouma, Susan HLTH:EX
Sent: Monday, December 18, 2017 10:45 AM
To: Scott, Pam HLTH:EX; Stearn, Anne HLTH:EX
Cc: Will, Jordan HLTH:EX
Subject: RE: Direction Required: 1099464 - ASA s.22

s.22

Sue

-----Original Message-----

From: Scott, Pam HLTH:EX
Sent: Monday, December 18, 2017 10:24 AM
To: Stearn, Anne HLTH:EX; Bouma, Susan HLTH:EX
Cc: Will, Jordan HLTH:EX
Subject: RE: Direction Required: 1099464 - ASA s.22

Unfortunately too late - Sue called as soon as she got our message that she needed to call and is engaged in conversation.

-----Original Message-----

From: Stearn, Anne HLTH:EX
Sent: Monday, December 18, 2017 10:19 AM
To: Bouma, Susan HLTH:EX
Cc: Scott, Pam HLTH:EX; Will, Jordan HLTH:EX
Subject: RE: Direction Required: 1099464 - ASA s.22

With my greatest apologies....

-----Original Message-----

From: Stearn, Anne HLTH:EX
Sent: Monday, December 18, 2017 10:18 AM

To: Bouma, Susan HLTH:EX
Cc: Scott, Pam HLTH:EX; Will, Jordan HLTH:EX
Subject: RE: Direction Required: 1099464 - ASA s.22

Jas just called.... requests that we hold off until this afternoon

-----Original Message-----

From: Bouma, Susan HLTH:EX
Sent: Monday, December 18, 2017 10:17 AM
To: Stearn, Anne HLTH:EX
Cc: Scott, Pam HLTH:EX; Will, Jordan HLTH:EX
Subject: Re: Direction Required: 1099464 - ASA s.22

Ok. On it, Will try now, s.22

Sue

Sent from my iPhone

> On Dec 18, 2017, at 10:12 AM, Stearn, Anne HLTH:EX <Anne.Stearn@gov.bc.ca> wrote:

>

> Hi Pam – as we were just saying.... The MO has not sent the email yet and will be making further edits and they would like the phone call to be made tc s.22 to be made asap this morning which will focus on the key point of s.22

s.22 Minister Dix will be doing media shortly and they've requested the call be made asap.

>

> Thank you all very much

>

>

> Anne Stearn

> Director, Office of the Deputy Minister 5th Floor - 1515 Blanshard

> Street, Victoria BC V8W 3C8 Phone (250) 952-3572 / e-mail:

> anne.stearn@gov.bc.ca

>

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>

>

>

> From: Scott, Pam HLTH:EX

> Sent: Monday, December 18, 2017 9:37 AM

> To: Stearn, Anne HLTH:EX

> Cc: Will, Jordan HLTH:EX; Bouma, Susan HLTH:EX

> Subject: Direction Required: 1099464 - ASA s.22

s.22

>

> Hi Anne,

>

> Sue Bouma has informed me that as of late Friday the email still hadn't been sent to s.22 and that Jasmyn was going to make edits. Sue indicated that if that was the case, she didn't want it going out under her name (Jordan agreed that it should be higher up).

>

> In the meantime, the MO/PO instructed Sue to call s.22 this morning. Can you advise if the email has been sent to s.22, and provide a copy of what was sent so that Sue's communication is accurate.

>

> Thanks,

> Pam

>

> From: Bouma, Susan HLTH:EX

> Sent: Friday, December 15, 2017 2:40 PM

> To: Will, Jordan HLTH:EX; Scott, Pam HLTH:EX; Peluso, Jenna HLTH:EX

> Cc: McClymont, Brenda HLTH:EX; Stearn, Anne HLTH:EX; Fougere, Brianna

> HLTH:EX; HLTH Corporate Operations HLTH:EX; Stevens, Sandy HLTH:EX;

> Burnham, Lindsey HLTH:EX; Andrachuk, Andrea HLTH:EX; Moneo, Mitch

> HLTH:EX; Lun, Eric HLTH:EX

> Subject: RE: 1099464 - ASA s.22

>

> Hi!

>

> Did our response not go out? I committed to the response going out early this week and it should have gone. Are you saying s.2 has not seen this yet?

>

> Can you elaborate on the technical details that are to be changed? This information below would be how we need to consider things going forward and is a hint that other options need to be explored.

>

> If I am to call s. again, I would appreciate having clearer direction on what exactly to say. Especially if s.2 has not seen this response yet.

>

> Thanks,

> Sue

>

> From: Will, Jordan HLTH:EX

> Sent: Friday, December 15, 2017 2:22 PM

> To: Scott, Pam HLTH:EX; Peluso, Jenna HLTH:EX

> Cc: McClymont, Brenda HLTH:EX; Bouma, Susan HLTH:EX; Stearn, Anne

> HLTH:EX; Fougere, Brianna HLTH:EX; HLTH Corporate Operations HLTH:EX;

> Stevens, Sandy HLTH:EX; Burnham, Lindsey HLTH:EX; Andrachuk, Andrea

> HLTH:EX; Moneo, Mitch HLTH:EX; Lun, Eric HLTH:EX

> Subject: FW: 1099464 - ASA s.22

> Importance: High

>

> Good afternoon Jenna,

>

> I have just been in touch with the Minister's Office who has now requested further action on this file. On instruction from the PO after receiving the attached email (yellow envelope), the MO has requested that we reach out to the

s.22 once again, this time with a focus on the following paragraph from our draft email s.22 Email

Response.docx) attached:

s.13,s.22

>
> Please let me know if there are any concerns with this approach. Otherwise, if I can have a quick update once the call is made, it would be very much appreciated.
>
> Thank you,
>
> JORDAN WILL
> Director, Executive Operations
> Office of the Deputy Minister
> Ministry of Health
>
> P: 250.952.1908 | Jordan.Will@gov.bc.ca<<mailto:Jordan.Will@gov.bc.ca>>
>
> From: HLTH Corporate Operations HLTH:EX
> Sent: Thursday, December 14, 2017 10:42 AM
> To: Dycke, Kassandra HLTH:EX; Singh, Jasmyn HLTH:EX
> Cc: Will, Jordan HLTH:EX; HLTH Corporate Operations HLTH:EX; Burnham,
> Lindsey HLTH:EX; Andrachuk, Andrea HLTH:EX; Fougere, Brianna HLTH:EX;
> Stearn, Anne HLTH:EX
> Subject: 1099464 - ASA^{s.22}
> CONSENT FORM -- RE: MEDIA REQUEST - SOOKE MIRROR NEWS -- Please please
> read. Thank you
> Importance: High
>
> As promised below, attached is the draft email response for your review, approved by Mitch Moneo. Please let me know when this is approved for program staff to send.
> Thanks so much,
> Kathy Simonson
> Documents Lead / Corporate Operations / DMO / Ministry of Health
> 5-3 1515 Blanshard St, Victoria BC V8W 3C8 Telephone 250 952-0998
> kathy.simonson@gov.bc.ca<<mailto:kathy.simonson@gov.bc.ca>>
> Warning: This email is intended only for the use of the individual or organization to whom it is addressed. It may contain information that is privileged or confidential. Any distribution, disclosure, copying, or other use by anyone else is strictly prohibited. If you have received this in error, please telephone or e-mail the sender immediately and delete the message.
>
> From: HLTH Corporate Operations HLTH:EX
> Sent: Thursday, December 14, 2017 10:11 AM
> To: Dycke, Kassandra HLTH:EX
> Cc: Will, Jordan HLTH:EX; HLTH Corporate Operations HLTH:EX; Burnham,
> Lindsey HLTH:EX; Andrachuk, Andrea HLTH:EX; Fougere, Brianna HLTH:EX;
> Stearn, Anne HLTH:EX

> Subject: 1099464 - ASA ^{s.22}
> CONSENT FORM -- RE: MEDIA REQUEST - SOOKE MIRROR NEWS -- Please please
> read. Thank you
> Importance: High
>
> Further to your request below, Pharmaceutical Services Division has asked that we forward the attached telephone response summary documents as a top priority update on the case. Mitch Moneo, ADM has approved.
>
> The email response requested is currently going through revisions requested by the ADM, but will be going through approvals shortly. We will send for your review once received.
> Thanks so much,
> Kathy Simonson
> Documents Lead / Corporate Operations / DMO / Ministry of Health
> 5-3 1515 Blanshard St, Victoria BC V8W 3C8 Telephone 250 952-0998
> kathy.simonson@gov.bc.ca<mailto:kathy.simonson@gov.bc.ca>
> Warning: This email is intended only for the use of the individual or organization to whom it is addressed. It may contain information that is privileged or confidential. Any distribution, disclosure, copying, or other use by anyone else is strictly prohibited. If you have received this in error, please telephone or e-mail the sender immediately and delete the message.
>
>
> From: Dycke, Kassandra HLTH:EX
> Sent: Friday, December 8, 2017 2:32 PM
> To: Burnham, Lindsey HLTH:EX
> Subject: ASAP case work FW: ^{s.22}
> CONSENT FORM -- RE: MEDIA REQUEST - SOOKE MIRROR NEWS -- Please please
> read. Thank you
> Importance: High
>
> Hi Lindsey,
>
> Please forward this on as case work, asap. ^{s.22} and urgent for ^{s.22}. I would appreciate if the Ministry could place a call to ^{s.22} as a top priority, to gather additional information that may be needed, and assure ^{s.2} this is receiving our soonest attention. Could I ask for a direct response to the constituent, but provided to me to review and approve before it is delivered?
>
> Thanks so much.
> Kass
>
> Kassandra Dycke
> Ministerial Assistant to
> Hon. Adrian Dix, Minister of Health
> Room 337 | Parliament Buildings, Victoria, BC | V8W 9V1 Office
> 250-953-3584 | Cell ^{s.17}
> kassandra.dycke@gov.bc.ca<mailto:kassandra.dycke@gov.bc.ca>
>
>
>
> From: Mitchell-Starkey, Maureen
> [mailto:Maureen.Mitchell-Starkey@leg.bc.ca]
> Sent: Friday, December 8, 2017 1:28 PM
> To: McConnell, Sheena PREM:EX; Dycke, Kassandra HLTH:EX; Holmwood, Jen

> PREM:EX
> Cc: Horgan.MLA, John LASS:EX; Frederiksen, Hans LASS:EX; Osborn, Lynn
> LASS:EX; Nash, Amber PREM:EX
> Subject: s.22 - CONSENT FORM -- RE:
> MEDIA REQUEST - SOOKE MIRROR NEWS -- Please please read. Thank you
>
> Amber – as requested I have attached s.22 consent form for s.22
>
> Contact Information:
>
> s.22
>
>
>
>
>
>
> Maureen Mitchell-Starkey | Constituency Assistant to Honourable John
> Horgan, MLA, Langford-Juan de Fuca
> #122 - 2806 Jacklin Road Victoria BC V9B 5A4 | P: 250-391-2801 | F:
> 250-391-2804
>
>
> From: s.22
> Sent: December 7, 2017 10:26 PM
> To: Horgan.MLA, John
> <John.Horgan.MLA@leg.bc.ca<mailto:John.Horgan.MLA@leg.bc.ca>>
> Subject: Please please read. Thank you
>
>
> Dear John Horgan,
>
>
>
> s.22

Page 047 to/à Page 051

Withheld pursuant to/removed as

s.22

Traverse, Chantal HLTH:EX

From: McClymont, Brenda HLTH:EX
Sent: Thursday, December 21, 2017 8:56 AM
To: Bouma, Susan HLTH:EX
Cc: Stevens, Sandy HLTH:EX
Subject: 1099464 - ASA s.22

Importance: High

Good Morning Sue, can you give us an update to what is going on with this one? It seems the eApproval is still with Sabine.

From: Bouma, Susan HLTH:EX
Sent: Friday, December 15, 2017 2:40 PM
To: Will, Jordan HLTH:EX; Scott, Pam HLTH:EX; Peluso, Jenna HLTH:EX
Cc: McClymont, Brenda HLTH:EX; Stearn, Anne HLTH:EX; Fougere, Brianna HLTH:EX; HLTH Corporate Operations HLTH:EX; Stevens, Sandy HLTH:EX; Burnham, Lindsey HLTH:EX; Andrachuk, Andrea HLTH:EX; Moneo, Mitch HLTH:EX; Lun, Eric HLTH:EX
Subject: RE: 1099464 - ASA s.22

Hi!

Did our response not go out? I committed to the response going out early this week and it should have gone. Are you saying s.2 has not seen this yet?

Can you elaborate on the technical details that are to be changed? This information below would be how we need to consider things going forward and is a hint that other options need to be explored.

If I am to call s.2 again, I would appreciate having clearer direction on what exactly to say. Especially if s.2 has not seen this response yet.

Thanks,
Sue

From: Will, Jordan HLTH:EX
Sent: Friday, December 15, 2017 2:22 PM
To: Scott, Pam HLTH:EX; Peluso, Jenna HLTH:EX
Cc: McClymont, Brenda HLTH:EX; Bouma, Susan HLTH:EX; Stearn, Anne HLTH:EX; Fougere, Brianna HLTH:EX; HLTH Corporate Operations HLTH:EX; Stevens, Sandy HLTH:EX; Burnham, Lindsey HLTH:EX; Andrachuk, Andrea HLTH:EX; Moneo, Mitch HLTH:EX; Lun, Eric HLTH:EX
Subject: FW: 1099464 - s.22
Importance: High

Good afternoon Jenna,

I have just been in touch with the Minister's Office who has now requested further action on this file. On instruction from the PO after receiving the attached email (yellow envelope), the MO has requested that we reach out to s.22 s.22 once again, this time with a focus on the following paragraph from our draft email s.22 Email Response.docx) attached:

Please let me know if there are any concerns with this approach. Otherwise, if I can have a quick update once the call is made, it would be very much appreciated.

Thank you,

JORDAN WILL
Director, Executive Operations
Office of the Deputy Minister
Ministry of Health

P: 250.952.1908 | Jordan.Will@gov.bc.ca

From: HLTH Corporate Operations HLTH:EX
Sent: Thursday, December 14, 2017 10:42 AM
To: Dycke, Cassandra HLTH:EX; Singh, Jasmyn HLTH:EX
Cc: Will, Jordan HLTH:EX; HLTH Corporate Operations HLTH:EX; Burnham, Lindsey HLTH:EX; Andrachuk, Andrea HLTH:EX; Fougere, Brianna HLTH:EX; Stearn, Anne HLTH:EX
Subject: 1099464 - ASA s.22 - CONSENT FORM -- RE: MEDIA REQUEST -
SOOKE MIRROR NEWS -- Please please read. Thank you
Importance: High

As promised below, attached is the draft email response for your review, approved by Mitch Moneo. Please let me know when this is approved for program staff to send.

Thanks so much,

Kathy Simonson
Documents Lead / Corporate Operations / DMO / Ministry of Health
5-3 1515 Blanshard St. Victoria BC V8W 3C8
Telephone 250 952-0998

kathy.simonson@gov.bc.ca

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From: HLTH Corporate Operations HLTH:EX
Sent: Thursday, December 14, 2017 10:11 AM
To: Dycke, Cassandra HLTH:EX
Cc: Will, Jordan HLTH:EX; HLTH Corporate Operations HLTH:EX; Burnham, Lindsey HLTH:EX; Andrachuk, Andrea HLTH:EX; Fougere, Brianna HLTH:EX; Stearn, Anne HLTH:EX
Subject: 1099464 - ASA s.22) - CONSENT FORM -- RE: MEDIA REQUEST -

SOOKE MIRROR NEWS -- Please please read. Thank you

Importance: High

Further to your request below, Pharmaceutical Services Division has asked that we forward the attached telephone response summary documents as a top priority update on the case. Mitch Moneo, ADM has approved.

The email response requested is currently going through revisions requested by the ADM, but will be going through approvals shortly. We will send for your review once received.

Thanks so much,

Kathy Simonson

Documents Lead / Corporate Operations / DMO / Ministry of Health

5-3 1515 Blanshard St, Victoria BC V8W 3C8

Telephone 250 952-0998

kathy.simonson@gov.bc.ca

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From: Dycke, Kassandra HLTH:EX

Sent: Friday, December 8, 2017 2:32 PM

To: Burnham, Lindsey HLTH:EX

Subject: ASAP case work FW: s.22

- CONSENT FORM -- RE: MEDIA REQUEST -

SOOKE MIRROR NEWS -- Please please read. Thank you

Importance: High

Hi Lindsey,

Please forward this on as case work, asap. s.22 and urgent for s.22 I would appreciate if the Ministry could place a call to s.22 as a top priority, to gather additional information that may be needed, and assure s.2 this is receiving our soonest attention. Could I ask for a direct response to the constituent, but provided to me to review and approve before it is delivered?

Thanks so much.

Kass

Kassandra Dycke

Ministerial Assistant to

Hon. Adrian Dix, Minister of Health

Room 337 | Parliament Buildings, Victoria, BC | V8W 9V1

Office 250-953-3584 | Cell s.17

kassandra.dycke@gov.bc.ca

From: Mitchell-Starkey, Maureen [<mailto:Maureen.Mitchell-Starkey@leg.bc.ca>]

Sent: Friday, December 8, 2017 1:28 PM

To: McConnell, Sheena PREM:EX; Dycke, Kassandra HLTH:EX; Holmwood, Jen PREM:EX

Cc: Horgan, MLA, John LASS:EX; Frederiksen, Hans LASS:EX; Osborn, Lynn LASS:EX; Nash, Amber PREM:EX

Subject: s.22

- CONSENT FORM -- RE: MEDIA REQUEST - SOOKE MIRROR

NEWS -- Please please read. Thank you

Amber – as requested I have attached s.22 consent form for s.22

Contact Information:

s.22

Maureen Mitchell-Starkey | Constituency Assistant to Honourable John Horgan, MLA, Langford-Juan de Fuca
#122 - 2806 Jacklin Road Victoria BC V9B 5A4 | P: 250-391-2801 | F: 250-391-2804

From s.22
Sent: December 7, 2017 10:26 PM
To: Horgan.MLA, John <John.Horgan.MLA@leg.bc.ca>
Subject: Please please read. Thank you

Dear John Horgan,

s.22

Page 056

Withheld pursuant to/removed as

s.22

Traverse, Chantal HLTH:EX

From: Will, Jordan HLTH:EX
Sent: Thursday, December 21, 2017 12:44 PM
To: Bouma, Susan HLTH:EX
Subject: RE: s.22 - IS HERE IN THE CO!!

Hi Sue,

Are you able to touch base in the next little bit regarding the timeline and your understanding of next steps for communicating with the doctor etc?

I'll be here most of the afternoon, in meetings from 2-3. Also, let me know if it would preferable for me to connect in elsewhere (ie Eric etc).

Thanks

JORDAN WILL
Director, Executive Operations
Office of the Deputy Minister
Ministry of Health

P: 250.952.1908 | Jordan.Will@gov.bc.ca

From: Bouma, Susan HLTH:EX
Sent: Monday, December 18, 2017 1:53 PM
To: Dycke, Kassandra HLTH:EX; Van Meer-Mass, Kate PREM:EX; Lun, Eric HLTH:EX; Singh, Jasmyn HLTH:EX
Cc: Stearn, Anne HLTH:EX; Will, Jordan HLTH:EX; Scott, Pam HLTH:EX; Gordon, Jason HLTH:EX
Subject: RE: s.22 IS HERE IN THE CO!!

Good Afternoon all:

s.22

Sue

From: Dycke, Kassandra HLTH:EX
Sent: Monday, December 18, 2017 1:10 PM
To: Van Meer-Mass, Kate PREM:EX; Lun, Eric HLTH:EX; Bouma, Susan HLTH:EX; Singh, Jasmyn HLTH:EX
Subject: RE: s.22 - IS HERE IN THE CO!!

Sorry – meant to cc you folks.

From: Dycke, Kassandra HLTH:EX
Sent: Monday, December 18, 2017 1:06 PM
To: Mitchell-Starkey, Maureen LASS:EX
Subject: RE: s.22 - IS HERE IN THE CO!!
Importance: High

Hi Moe – I have arranged for s.22 to be able to give Sue Bouma, Director of Special Authority in the Ministry of Health's Pharmaceutical Division, a call any time s.22
s.22

Sue Bouma can be reached through her Executive Assistant, Chantal, at 250-952-1090. I wanted to provide this number to s.22
s.22

I will leave this information in your hands to share with s.22 Please let me know if I can be of further assistance.

Cheers,
Kassandra

Kassandra Dycke
Ministerial Assistant to
Hon. Adrian Dix, Minister of Health
Room 337 | Parliament Buildings, Victoria, BC | V8W 9V1
Office 250-953-3584 | Cell s.17
kassandra.dycke@gov.bc.ca

From: Mitchell-Starkey, Maureen [<mailto:Maureen.Mitchell-Starkey@leg.bc.ca>]
Sent: Monday, December 18, 2017 12:55 PM
To: Van Meer-Mass, Kate PREM:EX; Dycke, Kassandra HLTH:EX; Mitchell-Starkey, Maureen LASS:EX
Subject: RE: s.22 - IS HERE IN THE CO!!

Thank you Kate, I did speak to Kassandra and s.22 has just left now. s.22
s.22 Moe

From: Van Meer-Mass, Kate PREM:EX [<mailto:Kate.VanMeer-Mass@gov.bc.ca>]
Sent: Monday, December 18, 2017 12:22 PM
To: Mitchell-Starkey, Maureen <Maureen.Mitchell-Starkey@leg.bc.ca>; Dycke, Kassandra HLTH:EX
<Kassandra.Dycke@gov.bc.ca>
Subject: RE: s.22 - IS HERE IN THE CO!!

Hi Kassandra,

Can you follow up with Moe and provide her with some language she can use to explain this decision?

Kate

From: Mitchell-Starkey, Maureen [<mailto:Maureen.Mitchell-Starkey@leg.bc.ca>]

Sent: Monday, December 18, 2017 11:59 AM

To: Dycke, Kassandra HLTH:EX; Nash, Amber PREM:EX; McConnell, Sheena PREM:EX; Van Meer-Mass, Kate PREM:EX; Singh, Jasmyrn HLTH:EX

Cc: Osborn, Lynn LASS:EX; Frederiksen, Hans LASS:EX; Mitchell-Starkey, Maureen LASS:EX

Subject: s.22 IS HERE IN THE CO!!

Importance: High

Hello Folks,

s.22

Can I please have someone call me with advise?

Thank you,
moe

Maureen Mitchell-Starkey | Constituency Assistant to Honourable John Horgan, MLA, Langford-Juan de Fuca
#122 - 2806 Jacklin Road Victoria BC V9B 5A4 | P: 250-391-2801 | F: 250-391-2804
E: Maureen.Mitchell-Starkey@leg.bc.ca
Office Hours: Monday to Friday, 10 am to 4 pm

MLA Website and to Sign up for John's Newsletter: [MLA John Horgan](#) | Twitter: [John Horgan](#) | Facebook: [John Horgan](#)





MY ITEMS	MY ASSIGNEE'S ITEMS	WATCHED ITEMS	CREATE	SUPPORT	SETTINGS	SUPER USER
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ITEM HISTORY

Enter one of the Item Numbers for the history you want to view and then hit Enter on your keyboard.

ID Number

Cliff Number

Other Number

Selected Item

Date Completed	ID	Cliff Number	Other Number	Subject
12/22/2017	23971	1100324		s.22

Approvals

Date Approved	User	Title
12/22/2017 11:32 AM	Bourne, Susan HLTH:EX	Item Approved

Comments

Comment Date	User	Title
12/22/2017 1:47 PM	Traverse, Chantal HLTH:EX	Fax response sent to s.22 i. File completed and closed
12/22/2017 11:32 AM	Bourne, Susan HLTH:EX	First RCD doesn't typically go to ED or ADMO but will for this one. do not send response until IN is approved by MO. if this comes in again, formal letter response will be assigned
12/21/2017 4:14 PM	Hodges-Whittaker, Diane HLTH:EX	Sue - as we discussed, this is s.22
12/19/2017 12:43 PM	Traverse, Chantal HLTH:EX	s.22 Over to you for action.
12/19/2017 12:11 PM	Traverse, Chantal HLTH:EX	Attached incoming, response template, patient background, and xref docs. Assigned to Special Authority to draft ADM response. Sent to drafter.
		CLIFF/eApp created

Path

Path Date	User	Title
12/22/2017 1:47 PM	Traverse, Chantal HLTH:EX	Item completed with the reason Completed.
12/22/2017 11:32 AM	Bourne, Susan HLTH:EX	Item sent to Traverse, Chantal.
12/21/2017 4:14 PM	Hodges-Whittaker, Diane HLTH:EX	Item sent to Bourne, Susan.
12/19/2017 12:43 PM	Traverse, Chantal HLTH:EX	Item sent to Hodges-Whittaker, Diane.
12/19/2017 12:11 PM	Traverse, Chantal HLTH:EX	Item Created.

DocumentPath

Upload Date	User	Title
12/22/2017 11:29 AM	Bourne, Susan HLTH:EX	Document [cana response2017] Uploaded.
12/21/2017 3:44 PM	Hodges-Whittaker, Diane HLTH:EX	Document [1100324 s.22 incoming] Uploaded.
12/19/2017 12:39 PM	Traverse, Chantal HLTH:EX	Document [xref 1099464 RE sJA] Uploaded.
12/19/2017 12:39 PM	Traverse, Chantal HLTH:EX	Document [xref 1099464 s.22 Telephone Response] Uploaded.
12/19/2017 12:39 PM	Traverse, Chantal HLTH:EX	Document [xref 1099464 s.22 Telephone Response] Uploaded.
12/19/2017 12:22 PM	Traverse, Chantal HLTH:EX	Document [1100324 background 20171219 CT] Uploaded.
12/19/2017 12:13 PM	Traverse, Chantal HLTH:EX	Document [ADM Letterhead (New Logo) Premiers awards 2-pager] Uploaded.
12/19/2017 12:11 PM	Traverse, Chantal HLTH:EX	Document [1100324 s.22 incoming] Uploaded.

 For support, email Hlth.eApprovals@gov.bc.ca.

Categories: FYI

[Downloaded from ascelibrary.org by University of California, San Diego on 06/08/14](#)

From: s.22

Hi,
Im wondering if you have heard of s.22
s.22

Sincerely,
s.22

Traverse, Chantal HLTH:EX

From: David Porte <David@porte.ca>
Sent: Wednesday, December 27, 2017 7:34 AM
To: adrian.dixmla@leg.bc.ca; Minister, HLTH HLTH:EX
Cc: Jennifer Wilson; OfficeofthePremier, Office PREM:EX
Subject: Canakinumab coverage for children with Systemic Juvenile Arthritis

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Invitations/Meeting Requests

Minister Dix,

I am following up on my two previous emails to you regarding the urgent need for action on providing Canakinumab to children in British Columbia who are suffering with Systemic Juvenile Arthritis (SJIA).

As you are no doubt aware from the letters you have received s.22

The executive director of our organization, The Cassie and Friends Society, has been in contact with your ministry to arrange a meeting to discuss this critical issue.

To date we have not received a reply to a meeting request. I am aware it is the holiday season and things are slower, however, at Cassie and Friends we pursue our mission regardless of the time of year.



We remain ready to meet at any time. Importantly we are ready with evidence-based criteria, for your review, that has been developed by the paediatric rheumatology specialists at BC Childrens for case by case evaluation of the use of Canakinumab for children with severe need. This will be ready to be presented and discussed at the meeting.

I look forward to your response as soon as possible so we can begin to work together to resolve this issue that has a serious and in some cases life threatening impacts on children in the province of British Columbia.

David Porte

Cassie and Friends Society for Children with Juvenile Arthritis and other Rheumatic Diseases T 604.732.7651 ext. 105 C
s.22

www.cassieandfriends.ca | david@porte.ca

MY ITEMS
MY ASSIGNEES
ITEMS
WATCHED ITEMS
CREATE
SUPPORT
SETTINGS
SUPER USER

ITEM HISTORY

Enter one of the Item Numbers or the history you want to view and then hit Enter on your keyboard.

ID Number

Cliff Number
1099737

Other Number

Selected Item

Date Completed	ID	Cliff Number	Other Number	Subject
1/7/2018	2375	1099737		Please to cover Cansikungh for their suffering from systemic juvenile arthritis.

Approvals

Date Approved	User	Title
1/22/2018 10:12 AM	Stevens, Sandy HLTH-EX	Item Approved
12/29/2017 12:01 PM	Chung, Elaine HLTH-EX	Item Approved
12/22/2017 2:36 PM	Whitaker, Susan HLTH-EX	Item Approved
12/20/2017 9:21 AM	Barker, Susan HLTH-EX	Item Approved

Comments

Comment Date	User	Title
1/7/2018 10:56 AM	Stevens, Sandy HLTH-EX	Approved, mailed letter, mailed pt to Premier, final package to Joyce Maglarus for all aspects of electronic filing. Advised CEO to close CLIFF log as assignment is completed.
1/5/2018 2:00 AM	Stevens, Sandy HLTH-EX	Elaine Chung approved this ED, sending to ADM, Mitch Monro for approval. Thanks!
12/29/2017 1:10 PM	Maglarus, Joyce HLTH-EX	Second wk removed, over to you.
12/29/2017 12:52 PM	McDermott, Brenda HLTH-EX	The 2 links and paragraphs in this letter are identical. Please check, thanks.
12/29/2017 12:35 PM	Maglarus, Joyce HLTH-EX	Approved by Elaine and Eric, over to you. Please note Elaine's comment in approval.
12/29/2017 12:01 PM	Chung, Elaine HLTH-EX	Approved as A/ED - please send to ADMD to begin for ADM approval
12/22/2017 10:44 AM	Whitaker, Susan HLTH-EX	Information about actual dollar cost added, as requested. I see you had already covered the info about exceptional case-by-case coverage. Please let me know if I can use this response for the other letters on coverage for Cansikungh.
12/21/2017 10:32 AM	Maglarus, Brenda HLTH-EX	Waiting for approval of a standard response for Cansikungh sent to Sue Barker Dec 21, 2017 11:09:33Z Kyle)
12/21/2017 9:52 PM	Barker, Susan HLTH-EX	I think we should outline just how much the treatment may end up being & wise and I don't think we need exceptional info for e 22
12/21/2017 9:00 PM	McDermott, Brenda HLTH-EX	For your review. Once you are satisfied with this response, I will use it for 1099737 Barker as well.
12/20/2017 10:51 AM	Travis, Cheryl HLTH-EX	Sent to Walter to add appropriate opening paragraph and to Premier and Minister.
12/20/2017 9:21 AM	Barker, Susan HLTH-EX	I believe this is to be the template response and will require appropriate address applied for each incoming.
12/19/2017 4:17 PM	Chung, Elaine HLTH-EX	Sending to DIR as per Elaine Chung (added away until Jan 9).
12/14/2017 12:31 PM	Barker, Susan HLTH-EX	Assigned to Special Authority for ADM response via Premier/Minister, pc both.
12/14/2017 10:23 AM	Stevens, Sandy HLTH-EX	Please assign for ADM response via Premier/Minister, pc both Template provided. Thanks!
12/14/2017 9:25 AM	Monro, Christine HLTH-EX	Please assign.

Path

Path Date	User	Title
1/22/2018 10:56 AM	Stevens, Sandy HLTH-EX	Item completed with the reason Completed.
1/7/2018 10:12 AM	Stevens, Sandy HLTH-EX	Item sent to McDermott, Brenda.
1/2/2018 7:03 AM	Stevens, Sandy HLTH-EX	Item sent to Monro, Mitch.
12/29/2017 1:10 PM	Maglarus, Joyce HLTH-EX	Item sent to McDermott, Brenda.
12/29/2017 12:52 PM	McDermott, Brenda HLTH-EX	Item sent to Maglarus, Joyce.
12/29/2017 12:35 PM	Maglarus, Joyce HLTH-EX	Item sent to McDermott, Brenda.
12/29/2017 12:01 PM	Chung, Elaine HLTH-EX	Item sent to Maglarus, Joyce.
12/29/2017 11:41 AM	Maglarus, Joyce HLTH-EX	Item sent to Chung, Elaine.
12/29/2017 9:21 AM	Barker, Susan HLTH-EX	Item sent to Chung, Eric.
12/22/2017 10:44 AM	Whitaker, Susan HLTH-EX	Item sent to Barker, Susan.
12/22/2017 10:32 AM	Whitaker, Susan HLTH-EX	Item sent to Whittaker, Susan.

12/21/2017 3:22 PM	Bouma, Susan HLTH-EX	Item sent to Hodges-Whittaker, Diane
12/21/2017 3:00 PM	Hodges-Whittaker, Diane HLTH-EX	Item sent to Bouma, Susan
12/20/2017 10:51 AM	Traverse, Chantal HLTH-EX	Item sent to Hodges-Whittaker, Diane
12/20/2017 9:21 AM	Bouma, Susan HLTH-EX	Item sent to Traverse, Chantal
12/19/2017 3:12 PM	Barr, Brittany JR HLTH-EX	Item sent to Bouma, Susan
12/14/2017 12:31 PM	Raine, Andrea L HLTH-EX	Item sent to Raine, Andrea
12/14/2017 10:33 AM	Stevens, Sandy HLTH-EX	Item sent to Raine, Andrea
12/14/2017 9:25 AM	Vincent, Christine E HLTH-EX	Item sent to McTygart, Brenda
12/14/2017 9:20 AM	Vincent, Christine E HLTH-EX	Item Created

DocumentPath

Upload Date	User	Title
12/14/2017 10:20 AM	Stevens, Sandy HLTH-EX	Document [AP01 Letterhead (New Logo) Premier's awards] Uploaded
12/14/2017 9:24 AM	Vincent, Christine E HLTH-EX	Document [10/9/2017 Kyle Training] Uploaded

For support, email ITBH.eApprovals@gov.bc.ca.



January 2, 2018

1099737

s.22

Dear s.22

Thank you for your letter of December 12, 2017, requesting PharmaCare coverage for canakinumab (Ilaris®) for the treatment of systemic Juvenile Idiopathic Arthritis (sJIA), on behalf of s.22

s.22 The Honourable John Horgan, Premier and the Honourable Adrian Dix, Minister of Health, have asked me to respond on their behalf.

I would first like to acknowledge s.22
s.22

Before talking about coverage for canakinumab for sJIA, I would first like to provide you with some information about the drug review process in British Columbia.

PharmaCare is the provincial program responsible for providing financial assistance for eligible prescription drugs and designated medical supplies. To ensure our services are sustainable, fair and effective, the Ministry of Health (the Ministry) requires all drugs undergo a rigorous, scientific review process. If the review process determines a drug has therapeutic advantages and cost-effectiveness advantages over established treatments, the Ministry considers adding the drug to the PharmaCare program formulary (a list of drugs eligible for coverage).

The Ministry makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs, priorities and resources, and the evidence-informed recommendations of an independent advisory body called the Drug Benefit Council (DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including: available clinical and pharmacoeconomic evidence (pharmacoeconomics is the branch of economics which compares the value of drugs); clinical practice and ethical considerations; input from patients, caregivers and patient groups provided through the Ministry's *Your Voice* web page; and the recommendations of the national Common Drug Review (CDR). The Ministry may also participate in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer, if applicable, and consider the outcomes of the pCPA's negotiation when making a listing decision for the drug.

...2

In 2016, the CDR reviewed canakinumab for the treatment of sJIA. On June 17, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released their recommendation advising that participating jurisdictions, including PharmaCare, add this drug to their formularies for the treatment of active sJIA in patients two years and older who have had an inadequate response or intolerance to oral steroids or methotrexate, with additional clinical criteria and conditions.

The CDEC noted that canakinumab is 10 to 15 times higher in price than other treatments for sJIA. The cost of canakinumab is approximately \$16,000 a vial with an annual cost of \$192,000 to \$798,000 per patient. The annual cost of tocilizumab (Actemra®), another biologic indicated for sJIA, ranges from \$9,402 to \$28,207 per patient.

The CDEC estimated that a price reduction of approximately 90 percent would be required to make canakinumab a cost-effective treatment option compared with tocilizumab.

The complete *CDEC Recommendation and Reasons for the Recommendation for canakinumab for sJIA* is available online at:

https://www.cadth.ca/sites/default/files/cdr/complete/SR0463_complete_laris_sJIA_June_21_16_e.pdf

Subsequently, the DBC reviewed canakinumab for sJIA and recommended that the Ministry not list it on the PharmaCare formulary at the manufacturer's submitted price. The DBC found that, although canakinumab was shown to be better than placebo (a harmless substance with no therapeutic effect) with regard to efficacy, there was insufficient evidence to determine if canakinumab would be effective in patients that are either intolerant to or have not responded to other biologics. Also, the DBC found that the drug was not cost-effective and did not offer optimal value for money.

The pCPA and Novartis, the manufacturer of canakinumab, discussed drug pricing for canakinumab; however, optimal value for money for the drug could not be achieved.

Based on the above, the Ministry decided, on January 10, 2017, to not add canakinumab to the PharmaCare formulary.

- 3 -

I appreciate this is not the response you were hoping for. We are aware that the Ministry's drug listing decisions have an impact on patients and their families; however, we must work within the limits of our resources.

Thank you for the opportunity to respond.

Sincerely,

A handwritten signature in black ink, appearing to read 'MKM', followed by a horizontal line.

Mitch Moneo
Assistant Deputy Minister
Pharmaceutical Services Division

pc: Honourable John Horgan
Honourable Adrian Dix

INFORMATION BULLETS

Cliff# 1101151 –Honourable John Horgan, Premier and MLA, Langford-Juan de Fuca,
re: PharmaCare coverage for canakinumab (Ilaris®) for the treatment of Systemic Juvenile
Idiopathic Arthritis (sJIA) s.22
s.22

REQUEST:

- Corporate Operations has requested an update on the Information Bullets previously provided on s.22 request for coverage of canakinumab, including any recent developments and the current status of the case.

BACKGROUND:

On December 7, 2017, the media contacted the Ministry about the case of a s.22
s.22

- s.22 also directly contacted the Premier's office, the Minister's office and the manufacturer, Novartis Pharmaceuticals.
- A petition to publicly fund canakinumab in BC received over 6,800 signatures as of December 21.
- sJIA is a type of chronic arthritis, affecting not only the joints but other parts of the body including the lymph nodes, heart, liver, lungs and spleen. Symptoms include daily fevers and a pink rash that can appear on different parts of the body. In addition, systemic symptoms including swollen lymph nodes, enlarged liver or spleen, and inflamed heart or lungs can take place at the same time as, or separately from, arthritis symptoms of joint swelling, stiffness, and pain.
- sJIA usually occurs before age five; most commonly at age two. Its cause is unknown and there is no cure. However, it is possible for the disease to go into remission. Some children grow out of it after receiving treatment.
- The following drugs can be used in Canada to treat sJIA:
 - Non-steroidal Anti-Inflammatory Drugs (NSAIDS), such as ibuprofen;
 - Corticosteroids, such as prednisone;
 - Disease-Modifying Anti-rheumatic Drugs (DMARDS), such as methotrexate;
 - tocilizumab (Actemra®) – a biologic administered as a bi-weekly intravenous (into a vein) infusion in the hospital that takes approximately 1 hour;
 - anakinra (Kinaret®) – a biologic administered as a daily subcutaneous (under the skin) injection that can take place in-office or at home with training. Note that:
 - anakinra is not officially approved by Health Canada for use sJIA; however, it is routinely used off-label for this indication; and
 - anakinra does not come early in the treatment line in clinical practice due to its inconvenient mode of administration. The subcutaneous injections appear to be particularly painful, especially for a population consisting of children, and are required daily. This has a significant impact on quality of life; and
 - canakinumab – a biologic administered as a monthly subcutaneous injection that can take place in-office or at home with training.

- Adalimumab (Humira®), abatacept (Orencia®), etanercept (Enbrel®) and infliximab (Remicade® or Inflectra™) are not indicated for sJIA, but may potentially be used for the treatment of sJIA. These biologics are Limited Coverage benefits for indications other than sJIA and most have practitioner exemptions for pediatric rheumatologists. However, it has since been determined that these products are not often used by BC clinicians.
- In 2016, the CDR reviewed canakinumab for the treatment of sJIA. On June 17, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released their recommendation advising that participating jurisdictions, including BC PharmaCare, add this drug to their formularies for the treatment of active sJIA in patients two years and older who have had an inadequate response or intolerance to oral steroids or methotrexate, assuming that: there was a substantial decrease in price so that the drug cost does not exceed the drug plan cost of tocilizumab; treatment is discontinued if there is no improvement after day 15; and patients are under the care of a physician experienced in treating sJIA.
- Subsequently, the Ministry's Drug Benefit Council (DBC) reviewed canakinumab for sJIA and recommended that the Ministry not list it on the PharmaCare formulary at the manufacturer's submitted price.
- Both the CDEC and the DBC noted that although canakinumab was shown to be better than placebo (a harmless substance with no therapeutic effect) with regard to efficacy, there was insufficient evidence to determine if canakinumab would be effective in patients who are either intolerant to or have not responded to other biologics.
- Also, both the CDEC and the DBC found that canakinumab was not cost-effective and did not offer optimal value for money. It is 10 to 15 times higher in price than other treatments for sJIA.
- The cost of canakinumab is approximately \$16,000 a vial with an annual cost of \$192,000 to \$798,000 per patient, depending on the patient's weight. The annual cost of tocilizumab ranges from \$9,402 to \$28,207 per patient. The annual cost of anakinra is \$20,000 per patient.
- The pan-Canadian Pharmaceutical Alliance (pCPA) started discussions with Novartis, but negotiations did not officially begin because Novartis would not agree to advance to negotiations based on the price reduction value recommended by the CDEC.

s.13,s.17

s.13,s.16,s.17

- Canakinumab is also indicated for Cryopyrin-Associated Periodic Syndrome (CAPS).
- Canakinumab for the treatment of CAPS received a 'do not list' recommendation from the CDEC due to a lack of clinical benefit.

s.13,s.17

s.13,s.16,s.17

FINDINGS:

- The cost-per-patient set by Novartis for canakinumab makes it difficult for it to be cost-effective and would adversely affect the long-term sustainability and affordability of the PharmaCare program. At the current price, canakinumab is not cost-effective nor cost-appropriate.
- The Ministry decided, on January 10, 2017, not to add canakinumab to the PharmaCare formulary.
- PharmaCare fully covers tocilizumab as a Limited Coverage benefit through its Special Authority program, and covers anakinra on an exceptional case-by-case basis.
- The Ministry is aware that PharmaCare drug listing decisions have an impact on patients and their families; however, we must work within the limits of our resources.
- Request for exceptional case-by-case coverage of drugs to treat sJIA are reviewed by a committee of three rheumatologists called the Rheumatology and Autoimmune Disease Drug Benefit Adjudication and Advisory Committee (the Expert Committee).
- The Expert Committee follows a peer-reviewed process to consider the medical details of each individual case to ensure that all appropriate treatment options have been explored, and makes recommendations.
- Coverage decisions are communicated directly back to the requesting physician, not to the patient.
- There are several therapy options available for sJIA.

s.22

SUGGESTED MLA RESPONSE:

- As above

Program ED/Branch/Division: Eric Lun / Drug Intelligence and Optimization / Pharmaceutical Services Division
Date: January 4, 2018

January 3, 2018

By email: premier@gov.bc.ca
hlth.minister@gov.bc.ca
eric.lun@gov.bc.ca

Honourable Premier
John Horgan
P.O. Box 9041
Stn Prov Govt
Victoria , BC V8W 9E1

Honourable Minister
Adrian Dix
Room 337 Parliament
Buildings
Victoria, BC V8V 1X4

Mr. Eric Lun
Executive Director, Drug Intelligence and Optimization
Ministry of Health Services
PO Box 9652
STN PROV GOVT
Victoria, BC V8W 9P4

Re: Coverage of Canakinumab^{s.22}

Dear Premier Horgan, Minister Dix, and Mr. Eric Lun

Happy New Year to you and yours.

s.22

Page 073 to/à Page 075

Withheld pursuant to/removed as

s.22

By email: premier@gov.bc.ca
adrian.dix.MLA@leg.bc.ca
eric.lun@gov.bc.ca

Honourable Minister Adrian Dix
Room 337 Parliament Buildings
Victoria, BC V8V 1X4

Honourable Premier John Horgan
P.O. Box 9041
Stn Prov Govt
Victoria, BC V8W 9E1

Mr. Eric Lun
Executive Director, Drug Intelligence and Optimization
Ministry of Health Services
PO Box 9652
STN PROV GOVT
Victoria, BC V8W9P4

Re: Coverage of Canakinumab

Dear Minister Dix, Premier Horgan and Mr. Eric Lun,

I am writing once again and crying out for your help in the urgent review of pharmacare coverage of canakinumab in BC. s.22

s.22

Page 077 to/à Page 078

Withheld pursuant to/removed as

s.22

January 3, 2018

By email: premier@gov.bc.ca
hlth.minister@gov.bc.ca
eric.lun@gov.bc.ca

Honourable Minister
Adrian Dix
Room 337 Parliament
Buildings
Victoria, BC V8V 1X4

Honourable Premier
John Horgan
P.O. Box 9041
STN PROV GOVT
Victoria , BC V8W 9E1

Mr. Eric Lun
Executive Director, Drug Intelligence and Optimization
Ministry of Health Services
PO Box 9652
STN PROV GOVT
Victoria, BC V8W9P4

Re: Coverage of Canakinumab^{s.22}

Dear Minister Dix, Premier Horgan, and Mr. Eric Lun,

s.22

Page 080

Withheld pursuant to/removed as

s.22

Traverse, Chantal HLTH:EX

From: Tyson, Jo HLTH:EX
Sent: Thursday, January 4, 2018 4:11 PM
To: Vincent, Christine E HLTH:EX
Subject: FW: revised version, thanks to lucinda - 1100026

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Assign

Please change this one from meeting request to PSD-Assign. I have imported the interim letter into the cliff log..

Thanks,
Jo

From: Stearn, Anne HLTH:EX
Sent: Thursday, January 4, 2018 2:01 PM
To: Tyson, Jo HLTH:EX; HLTH Corporate Operations HLTH:EX
Cc: Will, Jordan HLTH:EX
Subject: RE: revised version, thanks to lucinda - 1100026

Hi Jo - just got off the phone with Lucinda

Yes – email highlighted to Jennifer Wilson – no signature block, just ministry of health under the generic id
Yes – this is an interim response
Yes – assign to PSD
If you could, please send today with bcc Lucinda.

Dear Ms. Jennifer Wilson,

Thank you for your email. We are writing to acknowledge the receipt of the information and meeting request sent by Cassie and Friends. The Pharmaceutical Services Division (PSD) of the Ministry of Health will be following up on the received materials: PSD is responsible for the PharmaCare program, and for following an evidence-based decision making process, regarding formulary decisions. Input from patients, families and caregivers is part of this review process.

We understand that s.22 is a constituent of Vancouver-Mount Pleasant. If helpful to s.22 we would be pleased to copy her provincial representative, MLA Melanie Mark, on our correspondence.

Thank you

From: Tyson, Jo HLTH:EX
Sent: Wednesday, January 3, 2018 11:15 AM
To: Stearn, Anne HLTH:EX; HLTH Corporate Operations HLTH:EX
Cc: Will, Jordan HLTH:EX
Subject: RE: revised version, thanks to lucinda

Hi Anne

To confirm: we are talking about 1100026, currently logged as a meeting request and 'for review' with the MO

- We are to email the highlighted piece below to Jennifer Wilson – whose signature block?
- So this would be an interim response?
- Are we then to assign to PSD for ED sig and pc MLA Mark?

From: Stearn, Anne HLTH:EX
Sent: Wednesday, January 3, 2018 10:31 AM
To: Tyson, Jo HLTH:EX; HLTH Corporate Operations HLTH:EX
Cc: Will, Jordan HLTH:EX
Subject: revised version, thanks to lucinda

Hi Jo – late last week you and I were discussing the SJIA letter response that the Ministers Office had requested be send out via the Hlth email. I've attached the original incoming and it had an attachment as well. Below is the response that the MO requests be sent out to the correspondence.

Thanks very much

Anne Stearn

Director, Office of the Deputy Minister
5th Floor - 1515 Blanshard Street, Victoria BC V8W 3C8
Phone (250) 952-3572 / e-mail: anne.stearn@gov.bc.ca

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From: Singh, Jasmyn HLTH:EX
Sent: Saturday, December 30, 2017 12:53 PM
To: Stearn, Anne HLTH:EX
Cc: Yeung, Lucinda HLTH:EX
Subject: revised version, thanks to lucinda

Hi Anne. Here is a revised version, following Lucinda's edits. Let me know what you think.

Dear Ms. Jennifer Wilson,

Thank you for your email. We are writing to acknowledge the receipt of the information and meeting request sent by Cassie and Friends. The Pharmaceutical Services Division (PSD) of the Ministry of Health will be following up on the received materials: PSD is responsible for the PharmaCare program, and for following an evidence-based decision making process, regarding formulary decisions. Input from patients, families and caregivers is part of this review process.

We understand that s.22 is a constituent of Vancouver-Mount Pleasant. If helpful to s.22 we would be pleased to copy her provincial representative, MLA Melanie Mark, on our correspondence.

Thank you

Traverse, Chantal HLTH:EX

From: McClymont, Brenda HLTH:EX on behalf of hlth Pharmaceutical Services Correspondence Unit HLTH:EX
Sent: Thursday, January 4, 2018 8:12 AM
To: s.22
Subject: Ministry of Health Response - 1099967

1099967

s.22

Dear s.22 :

Thank you for your email of December 14, 2017, regarding PharmaCare coverage for canakinumab (Ilaris®) for the treatment of systemic Juvenile Idiopathic Arthritis (sJIA), s.22 The Honourable Adrian Dix, Minister of Health, has asked me to respond on his behalf.

Due to privacy considerations, I cannot make any specific comments regarding s.22 However, I can provide the following general information.

PharmaCare is the provincial program responsible for providing financial assistance for eligible prescription drugs and designated medical supplies. To ensure our services are sustainable, fair and effective, the Ministry of Health (the Ministry) requires all drugs undergo a rigorous, scientific review process. If the review process determines a drug has therapeutic advantages and cost effectiveness advantages over established treatments, the Ministry considers adding the drug to the PharmaCare program formulary (a list of drugs eligible for coverage).

The Ministry makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs, priorities and resources, and the evidence informed recommendations of an independent advisory body called the Drug Benefit Council (the DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including: available clinical and pharmacoeconomic evidence (pharmacoeconomics is the branch of economics which compares the value of drugs); clinical practice and ethical considerations; input from patients, caregivers and patient groups provided through the Ministry's Your Voice web page; and the recommendations of the national Common Drug Review (CDR). The Ministry may also participate in the pan Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer, if applicable, and consider the outcomes of the pCPA's negotiation when making a listing decision for the drug.

In 2016, the CDR reviewed canakinumab for the treatment of sJIA. On June 17, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released their recommendation advising that participating jurisdictions, including PharmaCare, add this drug to their formularies for the treatment of active sJIA in patients two years and older who have had an inadequate response or intolerance to oral steroids or methotrexate, with additional clinical criteria and conditions.

The CDEC noted that canakinumab is 10 to 15 times higher in price than other treatments for sJIA. The cost of canakinumab is approximately \$16,000 a vial with an annual cost of \$192,000 to \$798,000 per patient, depending on the patient's weight. The annual cost of tocilizumab (Actemra®), another biologic indicated for sJIA, ranges from \$9,402 to \$28,207 per patient.

The CDEC estimated that a price reduction of approximately 90 percent would be required to make canakinumab a cost effective treatment option compared with tocilizumab.

The complete CDEC Recommendation and Reasons for the Recommendation for canakinumab for sJIA is available online at: https://www.cadth.ca/sites/default/files/cdr/complete/SR0463_complete_ilaris_sJIA_June_21_16_e.pdf.

Subsequently, the DBC reviewed canakinumab for sJIA and recommended that the Ministry not list it on the PharmaCare formulary at the manufacturer's submitted price. The DBC found that, although canakinumab was shown to be better than placebo (a harmless substance with no therapeutic effect) with regard to efficacy, there was insufficient evidence to determine if canakinumab would be effective in patients who are either intolerant to or have not responded to other biologics. Also, the DBC found that the drug was not cost effective and did not offer optimal value for money.

The pCPA and Novartis Pharmaceuticals, the manufacturer of canakinumab, discussed drug pricing for canakinumab; however, optimal value for money for the drug could not be achieved.

Based on the above, the Ministry decided on January 10, 2017, to not add canakinumab to the PharmaCare formulary.

I appreciate this is not the response you were hoping for. We are aware that the Ministry's drug listing decisions have an impact on patients and their families; however, we must work within the limits of our resources.

Thank you for the opportunity to respond.

Sincerely,

Mitch Moneo
Assistant Deputy Minister
Pharmaceutical Services Division

pc:Honourable Adrian Dix

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-----Original Message-----

From: s.22
Sent: Thursday, December 14, 2017 8:02 AM
To: Dix.MLA, Adrian <Adrian.Dix.MLA@leg.bc.ca>
Cc: john.horgon.mla@leg.bc.ca
Subject: s.22

Dear Adrian,

s.22

happen to make this happen?!!

What if this was your child? What needs to

s.22

Traverse, Chantal HLTH:EX

From: Stevens, Sandy HLTH:EX on behalf of hlth Pharmaceutical Services Correspondence Unit
HLTH:EX
Sent: Thursday, January 4, 2018 7:49 AM
To: s.22
Subject: Ministry of Health Response 1099912

1099912

s.22

Dear ^{s.22}

Thank you for your emails of December 13, 2017 and December 17, 2017, regarding PharmaCare coverage for canakinumab (Ilaris) for systemic Juvenile Idiopathic Arthritis (sJIA), ^{s.22}

^{s.22} The Honourable Adrian Dix, Minister of Health, has asked me to respond on his behalf.

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Sincerely,

Mitch Moneo
Assistant Deputy Minister
Pharmaceutical Services Division

pc: Honourable Adrian Dix

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-----Original Message-----

From s.22

Sent: Sunday, December 17, 2017 9:38 PM

To: cbcnewsvanancouver@cbc.ca

Cc: Dix.MLA, Adrian <Adrian.Dix.MLA@leg.bc.ca>

Subject: s.22

Hi,

Im wondering if you have heard of s.22

s.22

s.22

Sincerely,
s.22

From: s.22
Sent: Wednesday, December 13, 2017 6:50 PM
To: Minister, HLTH HLTH:EX
Subject: s.22

s.22

I am writing in to show my support for s.22
s.22

s.22 On the government website it states, and I quote

“ Fairpharmacare also ensures that B.C. residents, REGARDLESS of income, are protected from catastrophic drug costs. “

s.22

he

I expect an email and some answers in regards to this matter.

Thank you for your time,

s.22

EMAIL RESPONSE

1099912

s.22

Dear s.22 :

Thank you for your emails of December 13, 2017 and December 17, 2017, regarding PharmaCare coverage for canakinumab (Ilaris) for systemic Juvenile Idiopathic Arthritis (sJIA),
s.22 The Honourable Adrian Dix,
Minister of Health, has asked me to respond on his behalf.

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In 2016, the CDR reviewed canakinumab for the treatment of sJIA. On June 17, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released their recommendation advising that participating jurisdictions, including PharmaCare, add this drug to their formularies for the treatment of active sJIA in patients two years and older who have had an inadequate response or intolerance to oral steroids or methotrexate, with additional clinical criteria and conditions.

The CDEC noted that canakinumab is 10 to 15 times higher in price than other treatments for sJIA. The cost of canakinumab is approximately \$16,000 a vial with an annual cost of \$192,000 to \$798,000 per patient, depending on the patient's weight. The annual cost of

tocilizumab (Actemra[®]), another biologic indicated for sJIA, ranges from \$9,402 to \$28,207 per patient.

The CDEC estimated that a price reduction of approximately 90 percent would be required to make canakinumab a cost-effective treatment option compared with tocilizumab.

The complete CDEC Recommendation and Reasons for the Recommendation for canakinumab for sJIA is available online at:

https://www.cadth.ca/sites/default/files/cdr/complete/SR0463_complete_Ilaris_sJIA_June_21_16_e.pdf.

Subsequently, the DBC reviewed canakinumab for sJIA and recommended that the Ministry not list it on the PharmaCare formulary at the manufacturer's submitted price. The DBC found that, although canakinumab was shown to be better than placebo (a harmless substance with no therapeutic effect) with regard to efficacy, there was insufficient evidence to determine if canakinumab would be effective in patients who are either intolerant to or have not responded to other biologics. Also, the DBC found that the drug was not cost-effective and did not offer optimal value for money.

The pCPA and Novartis, the manufacturer of canakinumab, discussed drug pricing for canakinumab; however, optimal value for money for the drug could not be achieved.

Based on the above, the Ministry decided, on January 10, 2017, to not add canakinumab to the PharmaCare formulary.

I appreciate this is not the response you were hoping for. We are aware that the Ministry's drug listing decisions have an impact on patients and their families; however, we must work within the limits of our resources.

Thank you for the opportunity to respond.

Sincerely,

Mitch Moneo
Assistant Deputy Minister
Pharmaceutical Services Division

pc: Honourable Adrian Dix

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ITEM HISTORY

Enter one of the Item Numbers for the history you want to view and then hit Enter on your keyboard.

ID Number

Cliff Number

1089912

Other Number

Selected Item

Date Completed	ID	Cliff Number ✓	Other Number	Subject
1/4/2018	23843	1089912	XREF 1089434 and 1089671	Questions regarding coverage of Casakimab for s.22

Approvals

Date Approved	User	Title
12/12/2018 4:38 PM	Monag, Mitch HLTH-EX	Item Approved
12/17/2017 5:26 PM	Chong, Elaine HLTH-EX	Item Approved
12/23/2017 4:29 PM	Bouma, Susan HLTH-EX	Item Approved
12/26/2017 9:25 AM	Bouma, Susan HLTH-EX	Item Approved

Comments

Comment Date	User	Title
1/4/2018 9:51 AM	Stevens, Sandy HLTH-EX	ADM approved, email sent, Doc, Lynde MacLennan for all aspects of electronic filing, advised CT to close CLIP for as assessment is now completed.
1/4/2018 9:27 AM	Stevens, Sandy HLTH-EX	Pulled back, ADM already approved.
1/4/2018 7:26 AM	Stevens, Sandy HLTH-EX	Elaine Chong approved via EO, sending to ADM, Mitch Monag for approval. Thanks!
12/20/2018 5:15 PM	McClennan, Brenda HLTH-EX	Approved by Elaine via Eric.
12/20/2018 11:17 AM	Tran, Michele HLTH-EX	Elaine approved as A/ED. Copy to Brenda.
12/17/2017 5:26 PM	Chong, Elaine HLTH-EX	Approved as A/ED. Please send to ADM to hold for ADM approval.
12/23/2017 4:29 PM	Bouma, Susan HLTH-EX	for approval via
12/22/2017 3:53 PM	Hodges-Whittaker, Diane HLTH-EX	For your review, I used wording similar to that used for 1089737 Kyle.
12/12/2017 10:46 AM	Hodges-Whittaker, Diane HLTH-EX	Waiting for approval of a template response on communications sent to Sue Bouma Dec 22, 2017 (1089737 Kyle).
12/11/2017 3:07 PM	Authier, Leticia HLTH-EX	Second iteming added.
12/6/2017 10:54 AM	Traverse, Chantal HLTH-EX	Sent to draft to draft response from ADM via Project. Can use wording from 1089737.
12/20/2017 9:25 AM	Bouma, Susan HLTH-EX	template response can be used for this iteming. If approved, please with ADM to confirm for responding to inquiries on this topic please.
12/19/2017 3:12 PM	Barry, Brittany JR HLTH-EX	Sent to DR as per Elaine Chong (Andria away until Jan 9).
12/16/2017 10:39 AM	Boyle, Andrea J HLTH-EX	Assigned to Special Authority for ADM signature via Project.
12/15/2017 9:23 AM	Stevens, Sandy HLTH-EX	Please assign for ADM signature via Project, template provided, DUE to ADM by Jan 9/18. Thanks!
12/15/2017 8:15 AM	Wardell, Christine E HLTH-EX	Please assign.

Path

Path Date	User	Title
1/4/2018 9:51 AM	Stevens, Sandy HLTH-EX	Item completed with the reason Completed.
1/4/2018 7:27 AM	Stevens, Sandy HLTH-EX	Item sent to McClennan, Brenda.
1/4/2018 7:26 AM	Stevens, Sandy HLTH-EX	Item sent to Monag, Mitch.
1/11/2018 4:38 PM	Monag, Mitch HLTH-EX	Item sent to McClennan, Brenda.
12/20/2018 5:15 PM	McClennan, Brenda HLTH-EX	Item sent to Monag, Mitch.
12/20/2018 11:17 AM	Tran, Michele HLTH-EX	Item sent to McClennan, Brenda.
12/17/2017 5:26 PM	Chong, Elaine HLTH-EX	Item sent to MacLennan, Lynde.
12/17/2017 4:29 PM	Bouma, Susan HLTH-EX	Item sent to Chong, Elaine.
12/23/2017 4:29 PM	Hodges-Whittaker, Diane HLTH-EX	Item sent to Bouma, Susan.
12/22/2017 10:46 AM	Hodges-Whittaker, Diane HLTH-EX	Item sent to Hodges-Whittaker, Diane.
12/23/2017 10:39 AM	Traverse, Chantal HLTH-EX	Item sent to Hodges-Whittaker, Diane.
12/20/2017 9:25 AM	Bouma, Susan HLTH-EX	Item sent to Traverse, Chantal.
12/19/2017 10:39 AM	Barry, Brittany JR HLTH-EX	Item sent to Bouma, Susan.
12/16/2017 10:39 AM	Boyle, Andrea J HLTH-EX	Item sent to Boyle, Andrea.

12/15/2017 9:23 AM	Stevens, Sandy H.H.H.EX	Item sent to Reins, Andrea.
12/15/2017 9:45 AM	Vincent, Christine E H.H.H.EX	Item sent to McClymont, Brenda.
12/15/2017 8:53 AM	Vincent, Christine E H.H.H.EX	Item Created.

DocumentPath

Upload Date	User	Title
12/21/2017 3:07 PM	Authier, Lisa M H.H.H.EX	Document (1699912 Baker 2nd incoming) Uploaded.
12/15/2017 10:40 AM	Reins, Andrea L H.H.H.EX	Document (1699621 Barker Telephone Response) Uploaded.
12/15/2017 9:21 AM	Stevens, Sandy H.H.H.EX	Document (Email Response) Uploaded.
12/15/2017 8:45 AM	Vincent, Christine E H.H.H.EX	Document (1699912 Barker Incoming) Uploaded.



For support, email Hith: eApprovals@gov.bc.ca.

EMAIL RESPONSE

1099967

s.22

Dear ^{s.22}

Thank you for your email of December 14, 2017, regarding PharmaCare coverage for canakinumab (Ilaris[®]) for the treatment of systemic Juvenile Idiopathic Arthritis (sJIA), ^{s.22}
^{s.22} The Honourable Adrian Dix, Minister of Health, has asked me to respond on his behalf.

Due to privacy considerations, I cannot make any specific comments regarding ^{s.22}
^{s.22} However, I can provide the following general information.

PharmaCare is the provincial program responsible for providing financial assistance for eligible prescription drugs and designated medical supplies. To ensure our services are sustainable, fair and effective, the Ministry of Health (the Ministry) requires all drugs undergo a rigorous, scientific review process. If the review process determines a drug has therapeutic advantages and cost effectiveness advantages over established treatments, the Ministry considers adding the drug to the PharmaCare program formulary (a list of drugs eligible for coverage).

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The CDEC estimated that a price reduction of approximately 90 percent would be required to make canakinumab a cost-effective treatment option compared with tocilizumab.

The complete CDEC Recommendation and Reasons for the Recommendation for canakinumab for sJIA is available online at:

https://www.cadth.ca/sites/default/files/cdr/complete/SR0463_complete_Ilaris_sJIA_June_21_16_e.pdf

Subsequently, the DBC reviewed canakinumab for sJIA and recommended that the Ministry not list it on the PharmaCare formulary at the manufacturer's submitted price. The DBC found that, although canakinumab was shown to be better than placebo (a harmless substance with no therapeutic effect) with regard to efficacy, there was insufficient evidence to determine if canakinumab would be effective in patients who are either intolerant to or have not responded to other biologics. Also, the DBC found that the drug was not cost-effective and did not offer optimal value for money.

The pCPA and Novartis Pharmaceuticals, the manufacturer of canakinumab, discussed drug pricing for canakinumab; however, optimal value for money for the drug could not be achieved.

Based on the above, the Ministry decided on January 10, 2017, to not add canakinumab to the PharmaCare formulary.

I appreciate this is not the response you were hoping for. We are aware that the Ministry's drug listing decisions have an impact on patients and their families; however, we must work within the limits of our resources.

Thank you for the opportunity to respond.

Sincerely,

Mitch Moneo
Assistant Deputy Minister
Pharmaceutical Services Division

pc: Honourable Adrian Dix

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ITEM HISTORY

Enter one of the Item Numbers for the history you want to view and then hit Enter on your keyboard.

ID Number

Cliff Number

1099967

Other Number

Selected Item

Date Completed	ID	Cliff Number✓	Other Number	Subject	
1/4/2018	23853	1099967	1099464 DUE to ADMO by Jan 5/18	s.22 disparately needs	deserves the medicine Canakinumab he so

Approvals

Date Approved	User	Title
1/2/2018 4:36 PM	Monea, Mitch HLTH:EX	Item Approved.
12/27/2017 5:27 PM	Cheng, Elaine HLTH:EX	Item Approved.
12/27/2017 4:37 PM	Bonma, Susan HLTH:EX	Item Approved.

Comments

Comment Date	User	Title
1/4/2018 8:12 AM	McClymont, Brenda HLTH:EX	Approved by Mitch Monea, email sent, bcc'd DIO for electronic filing
1/2/2018 3:37 PM	McClymont, Brenda HLTH:EX	Approved by Elaine aka Eric
1/2/2018 2:09 PM	Tran, Michelle HLTH:EX	Approved by Elaine as A/ED. Over to you.
12/27/2017 5:27 PM	Cheng, Elaine HLTH:EX	Approved as A/ED. Please send to ADMO to hold for ADM approval.
12/27/2017 4:37 PM	Bonma, Susan HLTH:EX	for approval A/ED
12/27/2017 3:08 PM	Hodges-Whittaker, Diane HLTH:EX	For your review. I used wording similar to 1099737 Kyle.
12/27/2017 10:48 AM	Hodges-Whittaker, Diane HLTH:EX	Waiting for approval of a template response on canakinumab sent to Sue Bonma Dec 22, 2017 (1099737 Kyle)
12/20/2017 6:18 AM	Traverse, Chantel HLTH:EX	Sent to Diane HW who is covering for Andrea.
12/15/2017 12:13 PM	Raine, Andrea L HLTH:EX	Assigned to Special Authority for ADM signature aka Minister, pc Minister.
12/15/2017 11:52 AM	Stevens, Sandy HLTH:EX	Please assign for LMA signature aka Minister, pc Minister, template provided. Due to ADM by Jan 5/18. Thanks!
12/15/2017 9:55 AM	Gambie, Suzanne H HLTH:EX	please assign

Path

Path Date	User	Title
1/4/2018 8:12 AM	McClymont, Brenda HLTH:EX	Item completed with the reason Completed.
1/2/2018 4:36 PM	Monea, Mitch HLTH:EX	Item sent to McClymont, Brenda.
1/2/2018 3:37 PM	McClymont, Brenda HLTH:EX	Item sent to Monea, Mitch.
1/2/2018 2:09 PM	Tran, Michelle HLTH:EX	Item sent to McClymont, Brenda.
12/27/2017 5:27 PM	Cheng, Elaine HLTH:EX	Item sent to Monea, Mitch.
12/27/2017 4:37 PM	Bonma, Susan HLTH:EX	Item sent to Cheng, Elaine.
12/27/2017 3:08 PM	Hodges-Whittaker, Diane HLTH:EX	Item sent to Bonma, Susan.
12/27/2017 10:48 AM	Hodges-Whittaker, Diane HLTH:EX	Item sent to Hodges-Whittaker, Diane.
12/20/2017 6:18 AM	Traverse, Chantel HLTH:EX	Item sent to Hodges-Whittaker, Diane.
12/15/2017 12:13 PM	Raine, Andrea L HLTH:EX	Item sent to Raine, Andrea.
12/15/2017 11:52 AM	Stevens, Sandy HLTH:EX	Item sent to Raine, Andrea.
12/15/2017 9:55 AM	Gambie, Suzanne H HLTH:EX	Item sent to McClymont, Brenda.
12/15/2017 9:55 AM	Gambie, Suzanne H HLTH:EX	Item Created.

DocumentPath

Upload Date	User	Title
12/15/2017 11:51 AM	Stevens, Sandy HLTH:EX	Document [Email Response] Uploaded.
12/15/2017 9:55 AM	Gambie, Suzanne H HLTH:EX	Document [1099967-McClymont-Canakinumab] Uploaded.



For support, email HRLEApprovals@gov.bc.ca.

Traverse, Chantal HLTH:EX

From: Jennifer Wilson <jennifer@cassieandfriends.ca>
Sent: Friday, January 5, 2018 4:44 PM
To: Health, HLTH HLTH:EX
Cc: Dix.MLA, Adrian LASS:EX; David Porte
Subject: 1100026-Wilson 6th Incoming

Categories: FYI

HLTH MO to PSD – add as 6th incoming to 1100026 – upload to CLIFF/eApps and advise divisional coordinator – dd

Dear Ministry of Health,

Thank you very much for your kind response and update. Our Chairman, David Porte, replied in full by email earlier today.

I also wanted address your comment about ^{s.22}

s.22

resides in the Vancouver-Kingsway riding and are constituents of Minister Dix,

MLA. ^{s.22}

s.22

They have requested a constituent meeting with Minister Dix MLA by way of their email and letter.

Thank you very much again for your office's responsiveness and attention to this matter.

Sincerely,
Jennifer

Jennifer Wilson
Executive Director
Cassie and Friends Society
604.617.1382
jennifer@cassieandfriends.ca
www.cassieandfriends.ca

On 4 January 2018 at 16:06, Health, HLTH HLTH:EX <HLTH.Health@gov.bc.ca> wrote:

Dear Ms. Wilson,

Thank you for your email. We are writing to acknowledge the receipt of the information and meeting request sent by Cassie and Friends. The Pharmaceutical Services Division (PSD) of the Ministry of Health will be following up on the received materials: PSD is responsible for the PharmaCare program, and for following an evidence-based decision making process, regarding formulary decisions. Input from patients, families and caregivers is part of this review process.

We understand that s.22 is a constituent of Vancouver-Mount Pleasant. If helpful to s.22 we would be pleased to copy her provincial representative, MLA Melanie Mark, on our correspondence.

Thank you,

Ministry of Health

From: Jennifer Wilson [mailto:jennifer@cassieandfriends.ca]

Sent: Wednesday, December 13, 2017 12:03 PM

To: Minister, HLTH HLTH:EX

Subject: RE: Coverage of Canakinumab

Hello Minister Dix,

Attached please find our letter about coverage of Canakinumab, as requested by your office.

s.22 We hope to meet with
you and that the BC government will quickly understand and act on the urgent need to take care of s.22
s.22 in BC suffering with SJIA.

The details are outlined in the attached letter.

I look forward to your reply and to arranging a meeting.

Jennifer

Jennifer Wilson

Executive Director

Cassie and Friends Society

604.617.1382

jennifer@cassieandfriends.ca

604.617.1382

Traverse, Chantal HLTH:EX

From: s.22
Sent: Monday, January 8, 2018 10:11 AM
To: Horgan.MLA, John LASS:EX; OfficeofthePremier, Office PREM:EX; Dix.MLA, Adrian LASS:EX; Health, HLTH HLTH:EX
Subject: For s.22 and all the other children suffering from autoinflammatory
Follow Up Flag: Follow up
Flag Status: Flagged
Categories: Christine

Dear John Horgan and Adrian Dix,

s.22

Page 098

Withheld pursuant to/removed as

s.22

Traverse, Chantal HLTH:EX

From: Heinze, Laura R GCPE:EX
Sent: Monday, January 8, 2018 12:16 PM
To: Bouma, Susan HLTH:EX; Forbes, Brooke GCPE:EX; Lun, Eric HLTH:EX
Cc: Anderson, Kristy GCPE:EX
Subject: RE: HLTH Media Request: Canakinumab

Thx – s.22
s.22

If easier, feel free to give me a call!

From: Bouma, Susan HLTH:EX
Sent: Monday, January 8, 2018 12:07 PM
To: Heinze, Laura R GCPE:EX; Forbes, Brooke GCPE:EX; Lun, Eric HLTH:EX
Subject: RE: HLTH Media Request: Canakinumab

Sure! s.22
s.22

From: Heinze, Laura R GCPE:EX
Sent: Monday, January 8, 2018 12:01 PM
To: Bouma, Susan HLTH:EX; Forbes, Brooke GCPE:EX; Lun, Eric HLTH:EX
Subject: RE: HLTH Media Request: Canakinumab

Thx Sue – could you touch base with us after you connect with BCCH? I would just like to have a sense of how the conversation went/what the feedback/reaction was...

From: Bouma, Susan HLTH:EX
Sent: Monday, January 8, 2018 11:58 AM
To: Forbes, Brooke GCPE:EX; Lun, Eric HLTH:EX
Cc: Heinze, Laura R GCPE:EX
Subject: RE: HLTH Media Request: Canakinumab

Hi Brooke!
s.22

Sue

From: Forbes, Brooke GCPE:EX
Sent: Monday, January 8, 2018 11:48 AM
To: Lun, Eric HLTH:EX; Bouma, Susan HLTH:EX
Cc: Heinze, Laura R GCPE:EX
Subject: FW: HLTH Media Request: Canakinumab

Hi Eric and Sue,

We received a follow up request on Ilaris.

We will be providing the same statement we sent to another outlet on Friday (at the bottom) and talk them through it, specifically highlighting RADBAAC.

Please let me know if you have any concerns.

Sue – are you still planning to speak with s.22 today?

Thanks,
Brooke

From: Laura Heinze [<mailto:Laura.Heinze@gov.bc.ca>]

Sent: Monday, January 8, 2018 11:12 AM

To: Heinze, Laura R GCPE:EX

Subject: HLTH Media Request: Canakinumab

Reporter

Neetu Garcha, Reporter

Global TV | BC

neetu.garcha@globalnews.ca

250-217-0970

Deadline ASAP

Request

I hope 2018 is off to a great start for both of you.

s.22

Is Adrian Dix available for an interview about this on camera today before 2pm?

Background

Recommendation

Due to patient confidentiality, we are unable to comment on specific cases.

PharmaCare uses physician specialist committees to review requests and provide coverage recommendations. In cases like this, a committee of three rheumatologists who are considered experts in the treatment involving the requested drug review requests for case-by-case coverage. In reviewing the request, the specialists would consider the medical

details of the case. They would look at all appropriate treatment options, what treatments have been explored already, other treatment options available to patients that PharmaCare provides coverage for – for example tocilizumab is fully covered under PharmaCare and anakinra is also available on an exceptional, case-by-case basis for sJIA patients – and then make recommendations. This is a peer-reviewed process.

Traverse, Chantal HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Monday, January 8, 2018 5:24 PM
To: Bouma, Susan HLTH:EX; Heinze, Laura R GCPE:EX; Forbes, Brooke GCPE:EX; Anderson, Kristy GCPE:EX; Moneo, Mitch HLTH:EX
Subject: RE: Hello.

s.13

From: Bouma, Susan HLTH:EX
Sent: Monday, January 8, 2018 4:32 PM
To: Heinze, Laura R GCPE:EX; Forbes, Brooke GCPE:EX; Anderson, Kristy GCPE:EX; Moneo, Mitch HLTH:EX; Lun, Eric HLTH:EX
Subject: Fwd: Hello.

Sue

Sent from my iPhone

Begin forwarded message:

s.22

Page 103 to/à Page 105

Withheld pursuant to/removed as

s.22

INFORMATION BULLETS

Cliff# –Honourable Adrian Dix, Minister of Health, re: PharmaCare coverage for canakinumab (Ilaris®) for the treatment of Systemic Juvenile Idiopathic Arthritis (sJIA) s.22
s.22

REQUEST:

- Executive Operations has requested an update on the Information Bullets previously provided on^{s.22} request for coverage of canakinumab, including any recent developments and the current status of the case.

BACKGROUND:

On December 7, 2017, the media contacted the Ministry about the case of a s.22
s.22

- s.22 also directly contacted the Premier's office, the Minister's office and the manufacturer, Novartis Pharmaceuticals.
- A petition to publicly fund canakinumab in BC has received over 16,000 signatures as of January 10.
- sJIA is a type of chronic arthritis, affecting not only the joints but other parts of the body including the lymph nodes, heart, liver, lungs and spleen. Symptoms include daily fevers and a pink rash that can appear on different parts of the body. In addition, systemic symptoms including swollen lymph nodes, enlarged liver or spleen, and inflamed heart or lungs can take place at the same time as, or separately from, arthritis symptoms of joint swelling, stiffness, and pain.
- sJIA usually occurs before age five; most commonly at age two. Its cause is unknown and there is no cure. However, it is possible for the disease to go into remission. Some children grow out of it after receiving treatment.
- The following drugs can be used in Canada to treat sJIA:
 - Non-steroidal Anti-Inflammatory Drugs (NSAIDS), such as ibuprofen;
 - Corticosteroids, such as prednisone;
 - Disease-Modifying Anti-rheumatic Drugs (DMARDS), such as methotrexate;
 - tocilizumab (Actemra®) – a biologic administered as a bi-weekly intravenous (into a vein) infusion in the hospital that takes approximately 1 hour;
 - anakinra (Kinaret®) – a biologic administered as a daily subcutaneous (under the skin) injection that can take place in-office or at home with training. Note that:
 - anakinra is not officially approved by Health Canada for use sJIA; however, it is routinely used off-label for this indication; and
 - anakinra does not come early in the treatment line in clinical practice due to its inconvenient mode of administration. The subcutaneous injections appear to be particularly painful, especially for a population consisting of children, and are required daily. This has a significant impact on quality of life; and
 - canakinumab – a biologic administered as a monthly subcutaneous injection that can take place in-office or at home with training.
 - Adalimumab (Humira®), abatacept (Orencia®), etanercept (Enbrel®) and infliximab (Remicade® or Inflectra™) are not indicated for sJIA, but may potentially be used for the

treatment of sJIA. These biologics are Limited Coverage benefits for indications other than sJIA and most have practitioner exemptions for pediatric rheumatologists. However, it has since been determined that these products are not often used by BC clinicians.

- In 2016, the CDR reviewed canakinumab for the treatment of sJIA. On June 17, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released their recommendation advising that participating jurisdictions, including BC PharmaCare, add this drug to their formularies for the treatment of active sJIA in patients two years and older who have had an inadequate response or intolerance to oral steroids or methotrexate, assuming that: there was a substantial decrease in price so that the drug cost does not exceed the drug plan cost of tocilizumab; treatment is discontinued if there is no improvement after day 15; and patients are under the care of a physician experienced in treating sJIA.
- Subsequently, the Ministry's Drug Benefit Council (DBC) reviewed canakinumab for sJIA and recommended that the Ministry not list it on the PharmaCare formulary at the manufacturer's submitted price.
- Both the CDEC and the DBC noted that although canakinumab was shown to be better than placebo (a harmless substance with no therapeutic effect) with regard to efficacy, there was insufficient evidence to determine if canakinumab would be effective in patients who are either intolerant to or have not responded to other biologics.
- Also, both the CDEC and the DBC found that canakinumab was not cost-effective and did not offer optimal value for money. It is 10 to 15 times higher in price than other treatments for sJIA.
- The cost of canakinumab is approximately \$16,000 a vial with an annual cost of \$192,000 to \$798,000 per patient, depending on the patient's weight. The annual cost of tocilizumab ranges from \$9,402 to \$28,207 per patient. The annual cost of anakinra is \$20,000 per patient.
- The pan-Canadian Pharmaceutical Alliance (pCPA) started discussions with Novartis, but negotiations did not officially begin because Novartis would not agree to advance to negotiations based on the price reduction value recommended by the CDEC.

s.13,s.17

s.13,s.16,s.17

- Canakinumab is also indicated for Cryopyrin-Associated Periodic Syndrome (CAPS).
- Canakinumab for the treatment of CAPS received a 'do not list' recommendation from the CDEC due to a lack of clinical benefit.

s.13,s.17

s.13,s.16,s.17

FINDINGS:

- The cost-per-patient set by Novartis for canakinumab makes it difficult for it to be cost-effective and would adversely affect the long-term sustainability and affordability of the PharmaCare program. At the current price, canakinumab is not cost-effective nor cost-appropriate.

- The Ministry decided, on January 10, 2017, not to add canakinumab to the PharmaCare formulary.
- PharmaCare fully covers tocilizumab as a Limited Coverage benefit through its Special Authority program, and covers anakinra on an exceptional case-by-case basis.
- The Ministry is aware that PharmaCare drug listing decisions have an impact on patients and their families; however, we must work within the limits of our resources.
- Request for exceptional case-by-case coverage of drugs to treat sJIA are reviewed by a committee of three rheumatologists called the Rheumatology and Autoimmune Disease Drug Benefit Adjudication and Advisory Committee (the Expert Committee).
- The Expert Committee follows a peer-reviewed process to consider the medical details of each individual case to ensure that all appropriate treatment options have been explored, and makes recommendations.
- Coverage decisions are communicated directly back to the requesting physician, not to the patient.
- There are several therapy options available for sJIA.

s.22

s.22

Advice:

s.13,s.22

Program ED/Branch/Division: Eric Lun / Drug Intelligence and Optimization / Pharmaceutical Services Division
Date: January 10, 2018

Traverse, Chantal HLTH:EX

From: Forbes, Brooke GCPE:EX
Sent: Wednesday, January 10, 2018 11:21 AM
To: Bouma, Susan HLTH:EX
Subject: RE: IBN for DIX, re ilaris

Thanks Sue!

From: Bouma, Susan HLTH:EX
Sent: Wednesday, January 10, 2018 11:20 AM
To: Forbes, Brooke GCPE:EX
Subject: FW: IBN for DIX, re ilaris

Updated IBN, not yet approved!

Mitch and I have discussed that media response focus really needs to indicate this is not last resort!

S

From: Bouma, Susan HLTH:EX
Sent: Wednesday, January 10, 2018 10:58 AM
To: Traverse, Chantal HLTH:EX; McClymont, Brenda HLTH:EX; Scott, Pam HLTH:EX
Cc: Moneo, Mitch HLTH:EX
Subject: IBN for DIX, re ilaris

Hi Chantal!

Please assign new CLIFF and e-Approve for this, assignment is IBN for MO re: ilaris coverage request for ^{s.22} due today to Sabine. Approval path-Mitch, then Sabine, to MO.

Sue

Susan Bouma, B.Sc. (Pharm), R.Ph, PharmD

Director, Special Authority Department
Drug Intelligence and Optimization Branch
Pharmaceutical Services Division
Ministry of Health

1515 Blanshard St
PO Box 9652 Stn Prov Govt
Victoria, BC, V8W 9P4
PH: 250-952-2506 FAX: 250-952-2216
e-mail: susan.bouma@gov.bc.ca

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anyone else is strictly prohibited. If you have received this in error, please telephone or e-mail the sender immediately and delete the message.

Traverse, Chantal HLTH:EX

From: Heinze, Laura R GCPE:EX
Sent: Wednesday, January 10, 2018 2:21 PM
To: Moneo, Mitch HLTH:EX
Cc: Forbes, Brooke GCPE:EX; Lun, Eric HLTH:EX; Bouma, Susan HLTH:EX; Anderson, Kristy GCPE:EX
Subject: RE: Ilaris LTE
Attachments: LTE_Ilaris_Jan 10 2018 DRAFT.docx

Thx- I've updated this version. I also edited the last sentence which was a duplicate to read:

We will continue to work with patients and physicians to help them navigate this process.

Does that work for you?

From: Moneo, Mitch HLTH:EX
Sent: Wednesday, January 10, 2018 1:20 PM
To: Heinze, Laura R GCPE:EX
Cc: Forbes, Brooke GCPE:EX; Lun, Eric HLTH:EX; Bouma, Susan HLTH:EX; Anderson, Kristy GCPE:EX
Subject: RE: Ilaris LTE

Agree with Eric's comments. Thanks.

From: Heinze, Laura R GCPE:EX
Sent: Wednesday, January 10, 2018 12:33 PM
To: Moneo, Mitch HLTH:EX
Cc: Forbes, Brooke GCPE:EX; Lun, Eric HLTH:EX; Bouma, Susan HLTH:EX; Anderson, Kristy GCPE:EX
Subject: FW: Ilaris LTE

Hi Mitch,

Over to you for your review here. The MO has been asking for this so hoping we can get it up to them today?

Thx!
Laura

From: Lun, Eric HLTH:EX
Sent: Tuesday, January 9, 2018 5:02 PM
To: Forbes, Brooke GCPE:EX; Bouma, Susan HLTH:EX
Cc: Anderson, Kristy GCPE:EX; Heinze, Laura R GCPE:EX
Subject: RE: Ilaris LTE

Hi Brooke -- Better. Thanks

From: Forbes, Brooke GCPE:EX
Sent: Tuesday, January 9, 2018 2:51 PM
To: Lun, Eric HLTH:EX; Bouma, Susan HLTH:EX
Cc: Anderson, Kristy GCPE:EX; Heinze, Laura R GCPE:EX
Subject: RE: Ilaris LTE

Thanks Eric.

What about a combination of the two:

s.13

Thanks,
Brooke

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Withheld pursuant to/removed as

s.13

B.C. boy denied \$19,000-per-month drug to ease 'crippling pain' for 3rd time

Sooke Mirror

Friday, January 5, 2018

By Dawn Gibson

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Traverse, Chantal HLTH:EX

From: Forbes, Brooke GCPE:EX
Sent: Wednesday, January 10, 2018 1:59 PM
To: Bouma, Susan HLTH:EX
Subject: Transcript

CBCV (CBC Victoria)
CBC On the Island
10-Jan-2018 08:12

Quoted: Jillian Lanthier, Gregor Craigie

Copyright

Page 118 to/à Page 119

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Copyright

INFORMATION BULLETS

Cliff# 1101722 – Honourable Adrian Dix, Minister of Health, re: PharmaCare coverage for canakinumab (Ilaris®) for the treatment of Systemic Juvenile Idiopathic Arthritis (sJIA) for s.22

REQUEST:

- Executive Operations has requested an update on the Information Bullets previously provided on s.22 request for coverage of canakinumab, including any recent developments and the current status of the case.

BACKGROUND:

On December 7, 2017, the media contacted the Ministry of Health (the Ministry) about the case of a s.22 s.22

- s.22
- also directly contacted the Premier's office, the Minister's office and the manufacturer, Novartis Pharmaceuticals.
 - A petition to publicly fund canakinumab in British Columbia has received over 16,000 signatures as of January 10, 2018.
 - sJIA is a type of chronic arthritis, affecting not only the joints but other parts of the body including the lymph nodes, heart, liver, lungs and spleen. Symptoms include daily fevers and a pink rash that can appear on different parts of the body. In addition, systemic symptoms including swollen lymph nodes, enlarged liver or spleen, and inflamed heart or lungs can take place at the same time as, or separately from, arthritis symptoms of joint swelling, stiffness, and pain.
 - sJIA usually occurs before age five; most commonly at age two. Its cause is unknown and there is no cure. However, it is possible for the disease to go into remission. Some children grow out of it after receiving treatment.
 - The following drugs can be used in Canada to treat sJIA:
 - Non-steroidal anti-inflammatory drugs (NSAIDS), such as ibuprofen;
 - Corticosteroids, such as prednisone;
 - Disease-modifying anti-rheumatic drugs (DMARDs), such as methotrexate;
 - tocilizumab (Actemra®) – a biologic administered as a bi-weekly intravenous (IV) (into a vein) infusion in the hospital that takes approximately one hour;
 - anakinra (Kinaret®) – a biologic administered as a daily subcutaneous (SQ) (under the skin) injection that can take place in-office or at home with training. Note that:
 - anakinra is not officially approved by Health Canada for use of treating sJIA; however, it is routinely used off-label for this indication; and
 - anakinra does not come early in the treatment line in clinical practice due to its inconvenient mode of administration. The SQ injections appear to be particularly painful, especially for a population consisting of children, and are required daily. This has a significant impact on quality of life; and
 - canakinumab – a biologic administered as a monthly SQ injection that can take place in-office or at home with training.

- Adalimumab (Humira®), abatacept (Orencia®), etanercept (Enbrel®) and infliximab (Remicade® or Inflectra®) are not indicated for sJIA, but may potentially be used for the treatment of sJIA. These biologics are Limited Coverage benefits for indications other than sJIA and most have practitioner exemptions for pediatric rheumatologists. However, it has since been determined that these products are not often used by BC clinicians.
- In 2016, the national Common Drug Review (CDR) reviewed canakinumab for the treatment of sJIA. On June 17, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released their recommendation advising that participating jurisdictions, including BC PharmaCare, add this drug to their formularies for the treatment of active sJIA in patients two years and older who have had an inadequate response or intolerance to oral steroids or methotrexate, assuming that: there was a substantial decrease in price so that the drug cost does not exceed the drug plan cost of tocilizumab; treatment is discontinued if there is no improvement after day 15; and patients are under the care of a physician experienced in treating sJIA.
- Subsequently, the Ministry's Drug Benefit Council (DBC) reviewed canakinumab for sJIA and recommended that the Ministry not list it on the PharmaCare formulary at the manufacturer's submitted price.
- Both the CDEC and the DBC noted that although canakinumab was shown to be better than placebo (a harmless substance with no therapeutic effect) with regard to efficacy, there was insufficient evidence to determine if canakinumab would be effective in patients who are either intolerant to or have not responded to other biologics.
- Also, both the CDEC and the DBC found that canakinumab was not cost-effective and did not offer optimal value for money. It is 10 to 15 times higher in price than other treatments for sJIA.
- The cost of canakinumab is approximately \$16,000 a vial with an annual cost of \$192,000 to \$798,000 per patient, depending on the patient's weight. The annual cost of tocilizumab ranges from \$9,402 to \$28,207 per patient. The annual cost of anakinra is \$20,000 per patient.
- The pan-Canadian Pharmaceutical Alliance (pCPA) started discussions with Novartis, but negotiations did not begin because Novartis would not agree to advance to negotiations based on the price reduction value recommended by the CDEC.

s.13,s.17

s.13,s.16,s.17

- Canakinumab is also indicated for Cryopyrin-Associated Periodic Syndrome (CAPS).
- Canakinumab for the treatment of CAPS received a 'do not list' recommendation from the CDEC due to a lack of clinical benefit.

s.13,s.17

s.13,s.16,s.17

FINDINGS:

- The cost-per-patient set by Novartis for canakinumab makes it difficult for it to be cost-effective and would adversely affect the long-term sustainability and affordability of the PharmaCare program. At the current price, canakinumab is not cost-effective nor cost-appropriate.
- On January 10, 2017, the Ministry decided not to add canakinumab to the PharmaCare formulary.
- PharmaCare fully covers tocilizumab as a Limited Coverage benefit through its Special Authority program, and covers anakinra on an exceptional case-by-case basis.
- The Ministry is aware that PharmaCare drug listing decisions have an impact on patients and their families; however, we must work within the limits of our resources.
- Request for exceptional case-by-case coverage of drugs to treat sJIA are reviewed by a committee of three rheumatologists called the Rheumatology and Autoimmune Disease Drug Benefit Adjudication and Advisory Committee (the Expert Committee).
- The Expert Committee follows a peer-reviewed process to consider the medical details of each individual case to ensure that all appropriate treatment options have been explored, and makes recommendations.
- Coverage decisions are communicated directly back to the requesting physician, not to the patient.
- There are several therapy options available for sJIA.

s.22

- Novartis contacted the prescribing physician on December 11 and Ministry staff on December 15 and January 4, 2018. Any potential negotiations on price for this agent with Novartis are required to go through the pCPA process.

s.22

s.22

Advice:

s.22

Program ED/Branch/Division: Eric Lun/Drug Intelligence and Optimization/Pharmaceutical Services Division
Date: January 10, 2018



MY ITEMS	MY ASSIGNEE'S ITEMS	WATCHED ITEMS	CREATE	SUPPORT	SETTINGS	SUPER USER
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ITEM HISTORY

Enter one of the Item Numbers for the history you want to view and then hit Enter on your keyboard.

ID Number

Cliff Number

Other Number

Selected Item

Date Completed	ID	Cliff Number	Other Number	Subject
1/11/2018	24615	1101722		Information Bullets re: PharmaCare coverage for canakinumab (Ilaris®) for the treatment of Systemic Juvenile Idiopathic Arthritis (sJIA) s.22

Approvals

Date Approved	User	Title
1/10/2018 2:14 PM	Bouma, Susan HLTH:EX	Item Approved.
1/10/2018 12:27 PM	Moneo, Mitch HLTH:EX	Item Approved.

Comments

Comment Date	User	Title
1/11/2018 3:33 PM	Hartlen, Debra A HLTH:EX	Closing as per comments below.
1/10/2018 4:28 PM	Fougere, Brianna HLTH:EX	Returning for closing. Bullets have been emailed to the Minister.
1/10/2018 2:47 PM	Hartlen, Debra A HLTH:EX	Back for your approval. Track changes left on for your reference. Thanks!
1/10/2018 2:20 PM	Stevens, Sandy HLTH:EX	URGENT: Adjusted as requested, track changes left on, sending to CO-Documents. Thanks!
1/10/2018 2:14 PM	Bouma, Susan HLTH:EX	adjusted as requested
1/10/2018 1:49 PM	Stevens, Sandy HLTH:EX	RUSH: Sending to DIR, Susan Bouma to address comment on last page of bullets from MO. Please keep track changes on and return to Brenda McClymont. Thanks!
1/10/2018 1:39 PM	Hartlen, Debra A HLTH:EX	Returning to have question in document addressed as per comment below. Thanks!
1/10/2018 1:34 PM	Fougere, Brianna HLTH:EX	Please return to program area to answer question on last page of bullets.
1/10/2018 1:12 PM	Hartlen, Debra A HLTH:EX	For your RUSH review/approval. Due to MO today. Approved by Mitch Moneo, ADM. Thanks!
1/10/2018 1:02 PM	McClymont, Brenda HLTH:EX	URGENT for today. Approved by Mitch Moneo
1/10/2018 12:10 PM	McClymont, Brenda HLTH:EX	For your urgent approval
1/10/2018 11:57 AM	Traverse, Chantal HLTH:EX	Attached info bullets. Sent to ADMO to forward to Mitch for approval.
1/10/2018 11:17 AM	Traverse, Chantal HLTH:EX	CLIFF/eApp created:

Path

Path Date	User	Title
1/11/2018 3:33 PM	Hartlen, Debra A HLTH:EX	Item completed with the reason Completed.
1/10/2018 4:28 PM	Fougere, Brianna HLTH:EX	Item sent to Corporate Ops - Documents.
1/10/2018 2:47 PM	Hartlen, Debra A HLTH:EX	Item sent to Feulgen, Sabine.
1/10/2018 2:20 PM	Stevens, Sandy HLTH:EX	Item sent to Corporate Ops - Documents.
1/10/2018 2:14 PM	Bouma, Susan HLTH:EX	Item sent to Stevens, Sandy.
1/10/2018 1:49 PM	Stevens, Sandy HLTH:EX	Item sent to Bouma, Susan.
1/10/2018 1:39 PM	Hartlen, Debra A HLTH:EX	Item sent to McClymont, Brenda.
1/10/2018 1:34 PM	Fougere, Brianna HLTH:EX	Item sent to Corporate Ops - Documents.
1/10/2018 1:12 PM	Hartlen, Debra A HLTH:EX	Item sent to Feulgen, Sabine.
1/10/2018 1:02 PM	McClymont, Brenda HLTH:EX	Item sent to Corporate Ops - Documents.
1/10/2018 12:27 PM	Moneo, Mitch HLTH:EX	Item sent to McClymont, Brenda.
1/10/2018 12:10 PM	McClymont, Brenda HLTH:EX	Item sent to Moneo, Mitch.

1/10/2018 11:57 AM	Traverse, Chantal HLTH:EX	Item sent to McClymont, Brenda.
1/10/2018 11:17 AM	Traverse, Chantal HLTH:EX	Item Created.

DocumentPath

Upload Date	User	Title
1/10/2018 11:25 AM	Traverse, Chantal HLTH:EX	Document [1101722 Information bulletins for MCO re Harris Case] Uploaded.
1/10/2018 11:25 AM	Traverse, Chantal HLTH:EX	Document [1101722 IBN for DIX re Harris] Uploaded.



For support, email hlth.eApprovals@gov.bc.ca.

Traverse, Chantal HLTH:EX

From: Bouma, Susan HLTH:EX
Sent: Tuesday, February 6, 2018 4:18 PM
To: Traverse, Chantal HLTH:EX
Subject: FW: s.22 sJIA cases
Attachments: canakinumab Jan 9 2018 - All Documents.html.docx

From: Stephanie Ensworth s.22
Sent: Thursday, January 11, 2018 3:00 PM
To: Bouma, Susan HLTH:EX; Gordon, Jason HLTH:EX
Subject: Fwd: s.22 sJIA cases

Hello again Sue and Jason,

Of note, in my documenting of my conversation with s.22 I only recorded exactly what was discussed; therefore, in the document I just sent to you, I did not put in any of my recommendations following my discussion with her because I did not discuss those with her.

Stephanie

----- Forwarded message -----

From: Stephanie Ensworth s.22
Date: Thu, Jan 11, 2018 at 2:54 PM
Subject: Fwd: s.22 sJIA cases
To: "Bouma, Susan HLTH:EX" <Susan.Bouma@gov.bc.ca>, "Gordon, Jason HLTH:EX" <Jason.Gordon@gov.bc.ca>
Cc: Stephanie Ensworth s.22

Hello Sue and Jason,

I attempted to record my conversation with s.22 on SharePoint in the folder on canakinumab but it did not work and I lost some of my work. Thus, I have typed it all out in a word document and attached it to this email so that you can put it wherever you would like to keep it. I hope this works for you. Please let me know if it doesn't.

Stephanie

----- Forwarded message -----

From: Gordon, Jason HLTH:EX <Jason.Gordon@gov.bc.ca>
Date: Thu, Jan 11, 2018 at 12:56 PM
Subject: RE: s.22 sJIA cases
To: Stephanie Ensworth s.22

Yes, that should work. If it doesn't please let me know and I can probably do some screen grabs on how it looks on my end when I upload files.

I have to run away until ~ 2:30 though!

Jason

From: Stephanie Ensworth ^{s.22}
Sent: Thursday, January 11, 2018 12:50 PM
To: Gordon, Jason HLTH:EX
Subject: Re: ^{s.22} sJIA cases

Hi Jason,

I just went into SharePoint to write my notes on my discussion with ^{s.22}. I opened the canukinamab file but I couldn't find anywhere that allowed me to add info. Do I click on "add new document?"

Stephanie

On Tue, Jan 9, 2018 at 3:36 PM, Gordon, Jason HLTH:EX <Jason.Gordon@gov.bc.ca> wrote:

If you are sending it out in the minutes we would need to keep it anonymous (e.g. ^{s.22} patient initials etc.). Basically how we do it usually. I hope that makes sense?

Jason

From: ^{s.22} [mailto:^{s.22}]
Sent: Tuesday, January 9, 2018 3:25 PM
To: Gordon, Jason HLTH:EX
Subject: RE: ^{s.22} sJIA cases

I'm not sure what you mean about keeping it anonymous. Don't I need to record that I discussed the case with ^{s.22} and therein use my ^{s.22}

Stephanie

Sent from Stephanie's Galaxy S7

----- Original message -----

From: "Gordon, Jason HLTH:EX" <Jason.Gordon@gov.bc.ca>

Date: 2018-01-09 3:09 PM (GMT-08:00)

To: s.22

Cc: "Gordon, Jason HLTH:EX" <Jason.Gordon@gov.bc.ca>

Subject: RE: s.22 SJIA cases

As long as you keep it anonymous I think that will be fine.

I had not thought to do it that way, but it works! Probably better than creating another document altogether.

Jason

From: s.22

Sent: Tuesday, January 9, 2018 3:02 PM

To: Gordon, Jason HLTH:EX

Subject: RE: s.22 SJIA cases

Okay, thanks, Jason.

Should I just write my notes in the section where you write notes for PharmaCare.....for example, where you just wrote the notes after talking with s.22

Stephanie

Sent from Stephanie's Galaxy S7

----- Original message -----

From: "Gordon, Jason HLTH:EX" <Jason.Gordon@gov.bc.ca>

Date: 2018-01-09 2:29 PM (GMT-08:00)

To: 'Stephanie Ensworth' s.22

Cc: "Gordon, Jason HLTH:EX" <Jason.Gordon@gov.bc.ca>

Subject: RE: s.22 sJIA cases

Oh, sorry about that. I was just tidying that up.

I put the case you contacted s.22 about back up on the SharePoint (it is once again in its own folder).

Jason

From: Stephanie Ensworth [mailto:s.22]
Sent: Tuesday, January 9, 2018 2:19 PM
To: Gordon, Jason HLTH:EX
Subject: Fwd: s.22 sJIA cases

Hi Jason,

In paragraph 2 below in Sue's email, she wants me to write some notes about my telephone discussion with s.22 from this morning. I, just now, went back into SharePoint to put this in and the sJIA cases have gone!?? What should I do about documenting that conversation? Is it possible to add that case back onto SharePoint? Please advise! Thanks in advance!

Stephanie

Page 130 to/à Page 131

Withheld pursuant to/removed as

s.22

Traverse, Chantal HLTH:EX

From: Heinze, Laura R GCPE:EX
Sent: Sunday, January 14, 2018 6:31 PM
To: Bouma, Susan HLTH:EX
Cc: Lun, Eric HLTH:EX; Moneo, Mitch HLTH:EX; Forbes, Brooke GCPE:EX; Anderson, Kristy GCPE:EX
Subject: Re: TNO: 'Like burning fire under my skin' - Tiffany Crawford - The Province

Thanks very much Sue!

Sent from my iPhone

On Jan 14, 2018, at 6:28 PM, Bouma, Susan HLTH:EX <Susan.Bouma@gov.bc.ca> wrote:

Hi, was out, sorry.

Yes both bullets are correct but would add that to the first one that the exemption for limited covered biologic agents has been provided as cases are reviewed by a committee of pediatric rheumatologists at BCCH prior to them being initiated.

(So considered to be similar to our adult review and criteria is still expected to be followed)

Sue

Sent from my iPhone

On Jan 14, 2018, at 6:14 PM, Lun, Eric HLTH:EX <Eric.Lun@gov.bc.ca> wrote:

Sorry but this info requires Sue to confirm. Sue, sorry to bother you but can you please review?

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization
Pharmaceutical Services Division
BC Ministry of Health

From: Heinze, Laura R GCPE:EX
Sent: Sunday, January 14, 2018 16:58
To: Lun, Eric HLTH:EX; Moneo, Mitch HLTH:EX
Cc: Bouma, Susan HLTH:EX; Forbes, Brooke GCPE:EX; Anderson, Kristy GCPE:EX
Subject: Re: TNO: 'Like burning fire under my skin' - Tiffany Crawford - The Province

Hi again

Sorry to keep bugging but are we good to share that second bullet?

Thx!

Laura

Sent from my iPhone

On Jan 14, 2018, at 1:40 PM, Lun, Eric HLTH:EX <Eric.Lun@gov.bc.ca> wrote:

Laura. Will ask Sue to confirm my two points which I have drafted to address your question:

1. For biologic drugs determined to be limited covered drug benefits by Pharmacare, pediatric rheumatologist currently are provided an 'exemption' from needing to complete Special Authority requests. This means that compared to rheumatologists who treat adults, these clinicians have been given broader latitude to prescribe with minimal need for prior authorizations from the Ministry.

2. For complex pediatric and Adult drug coverage requests like for non-benefits like anakinra and canakinumab, PCARE will consult from an expert panel of fellow rheumatologists. On an as needed basis, other clinical expertises are consulted if the particular expertise is not available on the expert panel, such as pediatric rheumatologists. Sue- not sure if any more detail can be share publicly or not.

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization
Pharmaceutical Services Division
BC Ministry of Health

From: Heinze, Laura R GCPE:EX

Sent: Sunday, January 14, 2018 13:19

To: Lun, Eric HLTH:EX

Cc: Bouma, Susan HLTH:EX; Forbes, Brooke GCPE:EX; Anderson, Kristy GCPE:EX

Subject: Fwd: TNO: 'Like burning fire under my skin' - Tiffany Crawford - The Province

Hi Eric,

I expect Jas has reached out to you as well, but they and the PO are looking for an answer to the question of pediatric specialists not being on the committee.

Are we able to say that they experts in their field and would consult with other specialists if they felt it necessary?

Thx!

Sent from my iPhone

Begin forwarded message:

From: <tno@gov.bc.ca>

Date: January 14, 2018 at 5:57:56 AM PST

To: Undisclosed recipients;;

Subject: TNO: 'Like burning fire under my skin' - Tiffany Crawford - The Province

'Like burning fire under my skin'

The Province

14-Jan-2018

Page A04

By Tiffany Crawford

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Page 135 to/à Page 137

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Copyright

Traverse, Chantal HLTH:EX

From: Hampson, Ashley PREM:EX
Sent: Monday, January 15, 2018 10:23 AM
To: Health, HLTH HLTH:EX
Subject: FW: For s.22 and all the other children suffering from
autoinflammatory

Follow Up Flag: Follow up
Flag Status: Flagged

Hi there,

Will Health be providing a response to the email below?

Ashley Hampson
Correspondence Officer
Office of the Premier
(250) 387-3539

From: s.22
Sent: Monday, January 8, 2018 10:11 AM
To: Horgan.MLA, John LASS:EX; OfficeofthePremier, Office PREM:EX; Dix.MLA, Adrian LASS:EX; Health, HLTH HLTH:EX
Subject: For s.22 and all the other children suffering from autoinflammatory

Dear John Horgan and Adrian Dix,

s.22

You have the opportunity to fund a drug that can give these children back their childhood. s.22
s.22

Page 139

Withheld pursuant to/removed as

s.22

Traverse, Chantal HLTH:EX

From: Bouma, Susan HLTH:EX
Sent: Thursday, January 18, 2018 9:22 AM
To: Barry, Brittany JR HLTH:EX
Subject: FW: Application needed for special authority branchRe: FOI Request - HTH-2018-80062

This is new incoming.

Sue

From: s.22
Sent: Wednesday, January 17, 2018 4:12 PM
To: Bouma, Susan HLTH:EX
Subject: Application needed for special authority branchRe: FOI Request - HTH-2018-80062

Hello Susan Bouma,

Laura Cameron has given me your email address as she informed me the information s.22 have requested comes from the special authority branch of pharmacare.
Please see email below. I would like to request

s.22

Please contact me and let me know if any forms are needed to filled out regarding this application. Please also let me know when to expect this information.

s.22

On Jan 17, 2018, at 3:29 PM, Cameron, Laura FIN:EX <Laura.1.Cameron@gov.bc.ca> wrote:

Good Afternoon s.22

Please feel free to email Sue Bouma directly with your request. Her email address is:
Susan.Bouma@gov.bc.ca.

Thank you,

Laura Cameron | FOI Analyst | Information Access Operations | Ministry of Citizens' Services
ph: (778) 698-8402 **e:** Laura.1.Cameron@gov.bc.ca | **m:** PO Box 9569, Stn Prov Gov, Victoria BC
V8W 9K1

From s.22

Sent: Wednesday, January 17, 2018 2:55 PM

To: Cameron, Laura FIN:EX

Subject: Re: FOI Request - HTH-2018-80062

Hello Laura

Is there an email address I can submit my request to for Sue Bouma at pharmacare special authority branch?

I was able to do an online request with the FOI here and would like to speed up the process without snail mail.

Please do not close this file until I am satisfied with your reply.

Thank you

s.22

On Jan 16, 2018, at 9:11 AM, Cameron, Laura FIN:EX <Laura.1.Cameron@gov.bc.ca> wrote:

Good Morning,

I am the analyst assigned to your request for records with the Ministry of Health. Your records include:

s.22

I have been informed by the Ministry of Health that the records you are seeking can be requested directly through the Ministry of Health's Special Authority Branch. As such, please redirect your written request to: c/o Sue Bouma - PharmaCare, Special Authority Branch, PO Box 9652 Stn. Prov. Gov, Victoria, BC, V8W 9P4.

Please respond to this email to confirm you wish to formally withdraw/close your FOI request.

Thank you,

Laura Cameron | FOI Analyst | Information Access Operations | Ministry of Citizens' Services

ph: (778) 698-8402 **e:** Laura.1.Cameron@gov.bc.ca | **m:** PO Box 9569, Stn Prov Gov, Victoria BC V8W 9K1



January 30, 2018

1100026

Mr. David Porte, Founder and Chairman, and
Ms. Jennifer Wilson, Executive Director
Cassie and Friends Society
100 – 33 East 8th Ave
Vancouver BC V5T 1R5

Dear Mr. Porte and Ms. Wilson:

Thank you for your emails of December 13, 17, 20, 2017, and January 5, 2018 regarding PharmaCare coverage of canakinumab (Ilaris[®]) for the treatment of systemic Juvenile Idiopathic Arthritis (sJIA). This letter is also intended to be a response to your attached letter from s.22 dated December 18, 2017. The Honourable Adrian Dix, Minister of Health, has asked me to respond on his behalf. I apologize for the delayed response.

I would first like to acknowledge the considerable difficulties children's health problems present and the challenges this creates for families. I recognize that the drug and other costs associated with children's health care are a significant concern.

Before talking about coverage for canakinumab for sJIA, I would like to provide you with some information about the drug review process in British Columbia.

PharmaCare is the provincial program responsible for providing financial assistance for eligible prescription drugs and designated medical supplies. To ensure our services are sustainable, fair and effective, the Ministry of Health (the Ministry) requires all drugs undergo a rigorous, scientific review process. If the review process determines a drug has therapeutic advantages and cost-effectiveness advantages over established treatments, the Ministry considers adding the drug to the PharmaCare program formulary (a list of drugs eligible for coverage).

The Ministry makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs, priorities and resources, and the evidence-informed recommendations of an independent advisory body called the Drug Benefit Council (the DBC).

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The DBC's advice to the Ministry is based upon a review of many considerations, including: available clinical and pharmacoeconomic evidence (pharmacoeconomics is the branch of economics which compares the value of drugs); clinical practice and ethical considerations; input from patients, caregivers and patient groups provided through the Ministry's *Your Voice* webpage; and the recommendations of the national Common Drug Review (CDR). The Ministry may also participate in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer, if applicable, and consider the outcomes of the pCPA's negotiation when making a listing decision for the drug.

In 2016, the CDR reviewed canakinumab for the treatment of sJIA. On June 17, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released their recommendation advising that participating jurisdictions, including BC PharmaCare, add this drug to their formularies for the treatment of active sJIA in patients two years and older who have had an inadequate response or intolerance to oral steroids or methotrexate, assuming that: there was a substantial decrease in price so that the drug cost does not exceed the drug plan cost of tocilizumab (Actemra®), another biologic indicated for sJIA; treatment is discontinued if there is no improvement after day 15; and patients are under the care of a physician experienced in treating sJIA.

The complete *CDEC Recommendation and Reasons for the Recommendation for canakinumab for sJIA* is available online at:
https://www.cadth.ca/sites/default/files/cdr/complete/SR0463_complete_Ilaris_sJIA_June_21_16_e.pdf.

Subsequently, the DBC reviewed canakinumab for sJIA and recommended that the Ministry not list it on the PharmaCare formulary at the manufacturer's submitted price.

Both the CDEC and the DBC noted that, although canakinumab was shown to be better than placebo (a harmless substance with no therapeutic effect) with regard to efficacy, there was insufficient evidence to determine if canakinumab would be effective in patients who are either intolerant to or have not responded to other biologics.

Also, both the CDEC and the DBC found that canakinumab was not cost effective and did not offer optimal value for money. The CDEC noted that canakinumab is 10 to 15 times higher in price than other treatments for sJIA.

The cost-per-patient for canakinumab set by Novartis, the manufacturer, makes it difficult for it to be cost effective and would adversely affect the long-term sustainability and affordability of the PharmaCare program. At the current price, canakinumab is not cost effective nor cost appropriate.

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The cost of canakinumab set by the manufacturer Novartis is approximately \$16,000 a vial with an annual cost of \$192,000 to \$798,000 per patient depending on the patient's weight. The annual cost of tocilizumab ranges from \$9,402 to \$28,207 per patient. The annual cost of anakinra (Kineret[®]), another biologic which is not officially approved by Health Canada for treating sJIA, but is routinely used off-label for this indication, is \$20,000 per patient.

The pCPA started discussions with Novartis, but negotiations did not officially begin because Novartis would not agree to advance to negotiations based on the price reduction value recommended by the CDEC.

Based on the above, the Ministry decided on January 10, 2017, to not add canakinumab to the PharmaCare formulary.

Requests for exceptional last resort case-by-case coverage of drugs to treat sJIA are reviewed by a committee of three rheumatologists called the Rheumatology and Autoimmune Disease Drug Benefit Adjudication and Advisory Committee (the Committee).

The Committee follows a peer-reviewed process to consider the medical details of each individual case to ensure that all appropriate treatment options have been explored and makes recommendations to the Ministry. Other experts may also be consulted to assist the Committee, such as consulting pediatric rheumatologists.

Mr. Porte states in his letter dated December 11, 2017, s.13,s.17
s.13,s.17

With respect to your request to meet, I would be pleased to meet you on behalf of the Ministry. I understand that a meeting with Pharmaceutical Services Division staff is being planned for later in February and I will try my best to attend this meeting as well. Due to privacy, for this meeting, it would not be appropriate to discuss specific patient cases but rather we are very interested to better understand your perspectives as well as discuss broader system and process-related matters.

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- 4 -

I hope this response provides some additional background around the Ministry's context around this matter. We are aware that the Ministry's drug listing decisions have an impact on patients and their families; however, we must work within the limits of our resources.

Sincerely,

A handwritten signature in black ink, appearing to read 'M Moneo', with a horizontal line extending from the end.

Mitch Moneo
Assistant Deputy Minister
Pharmaceutical Services Division

pc: Honourable Adrian Dix
Honourable Melanie Mark, MLA Vancouver-Mount Pleasant
s.22



MY ITEMS	MY ASSIGNMENTS	WATCHED ITEMS	CREATE	SUPPORT	SETTINGS	SUPER USER
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ITEM HISTORY

Enter one of the Item Numbers for the history you want to view and then hit Enter on your keyboard.

ID Number

Cliff Number

1100026

Other Number

Selected Item

Date Completed

1/30/2018

ID Cliff Number ✓ Other Number Subject

24354 1100026

Appeal to provide coverage for Carakoumab for s.22 and the very small number of children in BC suffering with SJIA.

Approvals

Date Approved

1/29/2018 12:49 PM

User

Moneo, Mitch HLTH:EX

Title

Item Approved.

1/25/2018 3:39 PM

Lun, Eric HLTH:EX

Item Approved.

1/23/2018 8:39 AM

Fazlagic, Tijana HLTH:EX

Item Approved

Comments

Comment Date

1/30/2018 6:53 AM

User

Stevens, Sandy HLTH:EX

Title

Approved, mailed, cc mailed to MLA Marks and Ms Hergasheimer. Final Package emailed to Joyce Maglanque for all aspects of electronic filing. advised CO to close CLIFF log as assignment is now completed.

1/29/2018 10:07 AM

Stevens, Sandy HLTH:EX

Sending to ADM, Mitch Moneo for approval. Thanks!

1/26/2018 4:21 PM

Maglanque, Joyce HLTH:EX

approved Eric, over to you.

1/26/2018 12:23 PM

Traverse, Chantal HLTH:EX

Correction: letter response *

1/26/2018 12:21 PM

Traverse, Chantal HLTH:EX

Proofed email response. Sent back to EA.

1/26/2018 11:38 AM

Maglanque, Joyce HLTH:EX

Please proof and then send back to me the final doc. Also remove attachments not needed in approvals.

1/25/2018 3:56 PM

Lun, Eric HLTH:EX

approved with adjustments as attached

1/23/2018 11:05 AM

Barry, Brittany JR HLTH:EX

Approved by DIR. Sending to ED for approval.

1/23/2018 9:39 AM

Fazlagic, Tijana HLTH:EX

approved

1/22/2018 2:37 PM

Hodges-Whittaker, Diane HLTH:EX

For your review, note that I did not include Honourable Mezhobie Mark in the list of PCs. a search using a map of the riding has shows that the writer, s.22 is not her constituent. She is a constituent of Honourable Adrian Dix.

1/5/2018 10:20 AM

Hodges-Whittaker, Diane HLTH:EX

For action

1/5/2018 10:33 AM

Traverse, Chantal HLTH:EX

Assigned to Special Authority to draft response from ADM obo Minister and pc MLA Mark as per MO instruction.

1/5/2018 8:53 AM

Stevens, Sandy HLTH:EX

Please assign for ADM response obo Minister (to both Wilson/Porte and pc MLA Mark). Template provided. Thanks!

1/4/2018 4:30 PM

Vincent, Christine E HLTH:EX

Please assign.

Path

Path Date

1/30/2018 6:53 AM

User

Stevens, Sandy HLTH:EX

Title

Item re-completed with the reason Completed.

1/29/2018 12:49 PM

Moneo, Mitch HLTH:EX

Item sent to McClymont, Brenda.

1/29/2018 10:57 AM

Stevens, Sandy HLTH:EX

Item sent to Moneo, Mitch.

1/26/2018 4:21 PM

Maglanque, Joyce HLTH:EX

Item sent to McClymont, Brenda.

1/26/2018 12:21 PM

Traverse, Chantal HLTH:EX

Item sent to Maglanque, Joyce.

1/25/2018 11:38 AM

Maglanque, Joyce HLTH:EX

Item sent to Traverse, Chantal.

1/23/2018 9:39 AM

Lun, Eric HLTH:EX

Item sent to Maglanque, Joyce.

1/23/2018 11:05 AM

Barry, Brittany JR HLTH:EX

Item sent to Lun, Eric.

1/23/2018 8:39 AM

Fazlagic, Tijana HLTH:EX

Item sent to Barry, Brittany.

1/22/2018 2:37 PM

Hodges-Whittaker, Diane HLTH:EX

Item sent to Fazlagic, Tijana.

1/5/2018 11:20 AM	Hodges-Whittaker, Diane HLTH:EX	Item sent to Hodges-Whittaker, Diane.
1/5/2018 6:53 AM	Stevens, Sandy HLTH:EX	Item sent to Raine, Andrea.
1/4/2018 4:30 PM	Vincent, Christine E HLTH:EX	Item sent to McClymont, Brenda.
1/4/2018 4:29 PM	Vincent, Christine E HLTH:EX	Item Created.

DocumentPath

Upload Date	User	Title
1/22/2018 2:32 PM	Hodges-Whittaker, Diane HLTH:EX	Document [Addresses for PC] Uploaded.
1/9/2018 8:20 AM	Gamble, Suzanne H HLTH:EX	Document [1100026-Wilson 6th Incoming] Uploaded.
1/5/2018 8:44 AM	Stevens, Sandy HLTH:EX	Document [ADM Letterhead (New Logo) Premier's Awards] Uploaded.
1/4/2018 4:35 PM	Vincent, Christine E HLTH:EX	Document [1100026 Porte 5th Incoming] Uploaded.
1/4/2018 4:35 PM	Vincent, Christine E HLTH:EX	Document [1100026 Porte 4th Incoming] Uploaded.
1/4/2018 4:34 PM	Vincent, Christine E HLTH:EX	Document [1100026 Porte 3rd Incoming] Uploaded.
1/4/2018 4:34 PM	Vincent, Christine E HLTH:EX	Document [1100026 Porte 2nd Incoming] Uploaded.
1/4/2018 4:34 PM	Vincent, Christine E HLTH:EX	Document [1100026 Porte Incoming] Uploaded.
1/4/2018 4:29 PM	Vincent, Christine E HLTH:EX	Document [1100026 Porte Incoming and NO Instructions] Uploaded.



For support, email HLTH.eApprovals@gov.bc.ca.



MY ITEMS	MY ASSIGNED ITEMS	WATCHED ITEMS	CREATE	SUPPORT	SETTINGS	SUPER USER
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ITEM HISTORY

Enter one of the Item Numbers for the history you want to view and then hit Enter on your keyboard.

ID Number

Cliff Number

1101139

Other Number

Selected Item

Date Completed

1/31/2018

ID	Cliff Number	Other Number	Subject
24263	1101139		Fee for coverage of Concomitant for their s.22 to treat Systemic Juvenile Idiopathic Arthritis.

Approvals

Date Approved

1/30/2018 4:20 PM
1/29/2018 4:47 PM
1/29/2018 11:36 AM
1/29/2018 10:21 AM
1/23/2018 8:46 AM
1/17/2018 11:16 AM

User	Title
Moreau, Mitch HLTH:EX	Item Approved.
van, Eric HLTH:EX	Item Approved.
Bourne, Susan HLTH:EX	Item Approved.
Gordon, Jason HLTH:EX	Item Approved.
Fazlagic, Tijana HLTH:EX	Item Approved.
Bourne, Susan HLTH:EX	Item Approved.

Comments

Comment Date

1/31/2018 6:48 AM
1/30/2018 9:35 AM
1/30/2018 6:45 AM
1/29/2018 4:47 PM
1/29/2018 11:50 AM
1/29/2018 10:21 AM
1/25/2018 9:38 AM
1/26/2018 12:31 PM
1/23/2018 12:41 PM
1/23/2018 11:45 AM
1/23/2018 8:46 AM
1/22/2018 11:13 AM
1/18/2018 11:12 AM
1/18/2018 10:07 AM
1/17/2018 11:16 AM
1/17/2018 10:36 AM
1/17/2018 10:25 AM
1/17/2018 9:43 AM
1/9/2018 11:43 AM
1/5/2018 10:51 AM
1/3/2018 4:20 PM

User	Title
Stevens, Sandy HLTH:EX	Email sent via generic account, per Premier, to Joyce Maglanque for all aspects of electronic filing, advised CD to close CLIFF log as assignment is now completed.
Stevens, Sandy HLTH:EX	PUSH: sending to ADM. Mitch Moreau for approval. Thanks!
Traverse, Chantal HLTH:EX	Email response approved by SA Director, and ED. Sent to ADM. SA history to be attached to email response.
van, Eric HLTH:EX	approved with changes as attached
Bourne, Susan HLTH:EX	looks good. mom has asked today when she might expect this.
Gordon, Jason HLTH:EX	I think I only updated two paragraphs towards the end of the response, but I did so based on our discussion today.
Hodges-Whitaker, Diane HLTH:EX	As requested.
Maglanque, Joyce HLTH:EX	Per email from Eric and Sandy, sending to you (for Eric) please draft an interim response to be sent out today. thanks.
Vincent, Christine E HLTH:EX	Per K. Simonsen, due date extension granted to Jan. 31st; please send interim response.
Berry, Brittany JR HLTH:EX	Approved by CDR. Sending to ED for approval. Comments left on for your consideration.
Fazlagic, Tijana HLTH:EX	approved - Eric please see my comment in the letter
Raine, Andrea L HLTH:EX	Revised draft, as per info re 3rd incoming, sent to Tijana Fazlagic plus Sue Bourne for review/approval.
Berry, Brittany JR HLTH:EX	Sending to Andrea as per Sue. See 3rd incoming and update response accordingly. Note that we will provide actual digital copies of historical documents in this case rather than dates only. Sue states that Jason has SA history.
Berry, Brittany JR HLTH:EX	Sending to Brittany (covering for Chantal)
Bourne, Susan HLTH:EX	with changes
Raine, Andrea L HLTH:EX	Sending to Sue Bourne and Diane HW for review/approval, as Diane already drafted the response for s.22
Gaff, Kim E HLTH:EX	Over to Andrea
Gaff, Kim E HLTH:EX	Assign
Traverse, Chantal HLTH:EX	Path and dates added. Sent back to drafter.
van, Eric HLTH:EX	2nd incoming uploaded. Please per Premier
Hodges-Whitaker, Diane HLTH:EX	Could you please add a Recommended Approval Route with intermediary due dates?

1/3/2018 1:52 PM	Stevens, Sandy HLTH:EX	Please assign for ADM signature also Minister, template provided. Thanks!
1/3/2018 1:09 PM	Vincent, Christine E HLTH:EX	Please assign.

Path

Path Date	User	Title
1/31/2018 6:48 AM	Stevens, Sandy HLTH:EX	Item completed with the reason Completed.
1/30/2018 4:28 PM	Monroe, Mitch HLTH:EX	Item sent to McClymont, Brenda.
1/30/2018 9:35 AM	Stevens, Sandy HLTH:EX	Item sent to Monroe, Mitch.
1/30/2018 8:45 AM	Traverse, Chantal HLTH:EX	Item sent to McClymont, Brenda.
1/29/2018 4:47 PM	Lun, Eric HLTH:EX	Item sent to Traverse, Chantal.
1/29/2018 11:36 AM	Bouma, Susan HLTH:EX	Item sent to Lun, Eric.
1/29/2018 10:21 AM	Gordon, Jason HLTH:EX	Item sent to Bouma, Susan.
1/29/2018 9:28 AM	Hodges-Whittaker, Diane HLTH:EX	Item sent to Gordon, Jason.
1/26/2018 12:31 PM	Haglanque, Joyce HLTH:EX	Item sent to Hodges-Whittaker, Diane.
1/23/2018 11:45 AM	Barry, Brittany JR HLTH:EX	Item sent to Lun, Eric.
1/23/2018 8:46 AM	Falagac, Tjiana HLTH:EX	Item sent to Barry, Brittany.
1/22/2018 11:13 AM	Raine, Andrea L HLTH:EX	Item sent to Falagac, Tjiana.
1/18/2018 11:12 AM	Barry, Brittany JR HLTH:EX	Item sent to Raine, Andrea.
1/18/2018 10:07 AM	Barry, Brittany JR HLTH:EX	Item sent to Barry, Brittany.
1/17/2018 11:16 AM	Bouma, Susan HLTH:EX	Item sent to Traverse, Chantal.
1/17/2018 10:56 AM	Raine, Andrea L HLTH:EX	Item sent to Bouma, Susan.
1/17/2018 10:25 AM	Graff, Kim E HLTH:EX	Item sent to Raine, Andrea.
1/17/2018 9:43 AM	Graff, Kim E HLTH:EX	Item sent to Graff, Kim.
1/5/2018 11:43 AM	Traverse, Chantal HLTH:EX	Item sent to Hodges-Whittaker, Diane.
1/3/2018 4:20 PM	Hodges-Whittaker, Diane HLTH:EX	Item sent to Traverse, Chantal.
1/2/2018 1:52 PM	Stevens, Sandy HLTH:EX	Item sent to Raine, Andrea.
1/2/2018 1:08 PM	Vincent, Christine E HLTH:EX	Item sent to McClymont, Brenda.
1/2/2018 1:07 PM	Vincent, Christine E HLTH:EX	Item Created.

DocumentPath

Upload Date	User	Title
1/30/2018 8:44 AM	Traverse, Chantal HLTH:EX	Document [1101139 SA history - attachment for email] Uploaded.
1/22/2018 10:29 AM	Raine, Andrea L HLTH:EX	Document [Background RE Application needed for special authority branch] Re FOI Request - HTH-2018-80062] Uploaded.
1/18/2018 11:09 AM	Barry, Brittany JR HLTH:EX	Document [1101139 3rd incoming FOI request] Uploaded.
1/5/2018 10:47 AM	Authier, Erica M HLTH:EX	Document [1101139 Prima 2nd incoming] Uploaded.
1/2/2018 1:51 PM	Stevens, Sandy HLTH:EX	Document [Email Response] Uploaded.
1/2/2018 1:07 PM	Vincent, Christine E HLTH:EX	Document [1101139 Prima Incoming] Uploaded.



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