Invokana National Settlement Agreement Compensation Protocol

1. Definitions

Unless otherwise indicated or required by context, capitalized terms in this Compensation Protocol have the meanings assigned to them in the Settlement Agreement.

In this protocol, the following terms shall have the meanings set forth below.

(a) **"Approved Claimant"** means a Settling Claimant that the Claims Administrator determines is eligible for compensation under the Compensation Protocol.

(b) **"Claim Form"** means the claim form developed by the Claims Administrator in consultation with Class Counsel and approved by the Court.

(c) **"Eligible Injury(s)"** means:

(i) a diagnosis of acute kidney injury or acute renal failure occurring on or before April 25, 2016;

(ii) a diagnosis of diabetic ketoacidosis occurring on or before August 31, 2016; or

(iii) amputation of a lower limb (i.e. leg, foot, or toe(s)) occurring on or before December 6, 2017

(d) **"Injury Evidence"** means proof, by way of medical records, which may include contemporaneous physician or hospital records supplemented by a letter from the physician providing any needed clarification of the contents of the records, of each Eligible Injury claimed.

(e) **"Prescription Evidence"** means the documentation that must be provided to:

(i) Establish proof of Invokana Product prescription for treatment of a diagnosis of diabetes through medical records or documentation from the prescribing or treating physician;

(ii) Establish proof of prescription for an Invokana Product(s), namely:

a. contemporaneous medical and/or pharmacy records demonstrating consumption of an Invokana Product;

b. contemporaneous insurance benefit records demonstrating coverage for an Invokana Product; or

c. documentation from the prescribing or treating physician confirming consumption of an Invokana Product;

(iii) Establish the requisite length of time of Invokana Product usage for each Eligible Injury claimed, as follows:

a. 7 days of continuous usage, including within 48 hours prior to the event, for a diagnosis of acute kidney injury or acute renal failure;

b. 7 days of continuous usage, including within 48 hours prior to the event, for a diagnosis of diabetic ketoacidosis;

c. 30 days of continuous usage, including within 30 days of the procedure, for amputation of a lower limb;

Proof of usage to be established with contemporaneous medical and/or pharmacy records, or contemporaneous insurance benefit records, or documentation from the prescribing or treating physician. Absent clear evidence to the contrary, it will be presumed that the Invokana Product prescription was filled and taken in accordance with the prescription.

(f) **"Referee"** means the person, selected by Class Counsel and approved by the Court, that will hear appeals from decisions of the Claims Administrator.

2. Purpose of the Compensation Protocol

The purpose of the Compensation Protocol is to provide further guidance to the Claims Administrator to help ensure that:

(a) only Class Members who satisfy the eligibility criteria set out in this protocol will receive compensation from the Net Settlement Proceeds;

(b) similarly situated Approved Claimants will be treated as uniformly as possible; and

(c) Approved Claimants will receive timely compensation in a way that minimizes, to the extent reasonably possible, the Claims Administration Costs and other transaction costs associated with implementation and administration of the Settlement Agreement.

3. Claimant Eligibility

To be eligible to receive a settlement payment pursuant to the Settlement Agreement, a Settling Claimant must:

(a) be, or if acting in a representative capacity, be representing the interest of a Canadian resident; and

(b) provide Injury Evidence for at least one Eligible Injury; and

(c) provide Prescription Evidence of `use of an Invokana Product at the time of, or prior to, such Eligible Injury; and

(d) In the event that the Eligible Injury(s) occurred within 3 months after the addition of relevant warning language to a Dear Health Care Professional Letter or Product Monograph (for acute kidney injury claims, after January 25, 2016; for diabetic ketoacidosis claims, after May 31, 2016; and for limb loss claims, after September 6, 2017), provide evidence that the Settling Claimant (i) started using an Invokana Product at least 30 days before the date of the Eligible Injury and (ii) continuously used an Invokana Product from such date to the time of the Eligible Injury without having either attended his or her prescribing physician or had their prescription renewed otherwise. This evidence may be established by way of medical or pharmacy records, or by way of Declaration; and

(e) properly complete, execute and submit a Claim Form to the Claims Administrator by the Claim Deadline.

4. Incomplete or Late Claim Forms

Claims that are not properly and timely submitted to the Claims Administrator by the relevant Claim Deadline will be denied by the Claims Administrator. For greater clarity, the failure to meet the relevant Claim Deadline with the required evidence will result in rejection of the claim.

5. Claim Processing Guidelines

If, during claims processing, the Claims Administrator finds technical deficiencies in a Settling Claimant's Claim Form or Evidence, the Claims Administrator shall notify the Settling Claimant of the technical deficiencies and shall allow the Settling Claimant 60 days from the date of mailing to correct the deficiencies. Such notification shall be by way of letter sent via email, if available, or through first class regular mail.

If the deficiencies are not corrected within the 60-day period, the Claims Administrator shall reject the claim and the Settling Claimant shall have no further opportunity to correct the deficiencies.

"Technical deficiencies" shall not include missing the Claim Deadline or failure to provide sufficient evidence to support the Settling Claimant's claim. In the event that a Settling Claimant has requested but not yet received the Evidence, the Settling Claimant may submit true copies of the records requests that were made requesting the Evidence, and the failure to provide that Evidence will be deemed a "technical deficiency".

6. Provincial Health Insurer Rights of Recovery

The Provincial Health Insurers will be paid from the Health Care Recovery Fund in aggregate for each jurisdiction in a manner proportionate to the number of Approved Claimants from each jurisdiction.

7. Settling Claimant Notification and Claim Appeals

(a) Notification

The Claims Administrator shall notify each Settling Claimant by way of a letter sent via email, if available, or through first class regular mail as to the approval or rejection of his or her claim and the points awarded to the Settling Claimant.

(b) Appeals

Settling Claimants will be granted a 30 day period from the date notice was sent to appeal the rejection and/or classification of their claims. Appeals will be reviewed and assessed by the Referee. Appeals will be made in writing to the Referee, supported only by the documentation provided to the Claims Administrator. Following the outcome on appeal, there shall be no right of further appeal or review. Costs of $150.00 will be payable by the Class Member in respect of an unsuccessful appeal.

8. **Payment of Funds and Stale Dating**

The Claims Administrator shall select the most cost-effective method possible to make payments to the relevant Provincial Health Insurers as may be required and to each Approved Claimant provided the payment recipient is able to accept funds in that manner.

Cheques shall be issued such that they are stale-dated six months after issuance. Cheques that are not cashed and become stale-dated will be re-issued in the Claims Administrator's sole discretion based on the circumstances of the case, and at the expense of the individual requesting the re-issuance. In no circumstances will cheques be reissued after the passage of six (6) months from the date on which the first cheque became stale-dated. In no case will a third cheque be issued.

9. **Allocation of Settlement**

The Net Settlement Proceeds will be allocated among the Approved Claimants in proportion to the cumulative points they are awarded under this Compensation Protocol.

10. **Optional Risk Factor Adjustment**

Class Members may seek a risk factor adjustment to increase their cumulative point value by fifty percent (50%). In order to claim the risk factor adjustment, Class Members must submit a Risk Factor Declaration and a copy of their general practitioner's medical records for the 2 years before their Eligible Injury.

11. **Allocation of Points**

Approved Claimants will be assigned points at the sole discretion of the Claims Administrator, subject to the right of appeal provided herein. The Claims Administrator will assign points based on the totality of the information and resources available to it, using its best judgment and expertise to fairly and reasonably adjudicate claims. In the event that an Approved Claimant meets the criteria for more than one injury level, the Approved Claimant shall receive the cumulative number of points allocated to each Injury level.

BASE POINTS		
LEVEL	**DESCRIPTION**	**POINTS**
Level 1 Acute Kidney Injury(s)		
1a	Acute Kidney Injury.	8 points
1b	Renal Replacement Therapy. *continuous hemofiltration, hemodialysis, intermittent hemodialysis, or peritoneal dialysis	4 points
1c	Prolonged Renal Replacement Therapy. *Approved Claimants shall receive 2 additional points where Renal Replacement Therapy was required for 6 or more months and therefore prolonged	2 points

1d	Death resulting from Acute Kidney Injury or acute renal failure.	2 points
Maximum Level 1 points = 16		
Level 2 Lower Limb Loss		
2a	Amputation of leg above the knee. *Approved Claimants receiving points for amputation of leg above the knee shall receive no points pursuant to 2b to 2i	32 points
2b	Amputation of leg below the knee. *Approved Claimants receiving points for amputation of leg below the knee shall receive no points pursuant to 2a or 2c to 2i	28 points
2c	Amputation of foot. *amputation at the ankle, also known as a Symes amputation, midtarsal amputation, also known as a Chopart amputation, tarsometatarsal amputation, also known as a Lisfranc amputation, or transmetatarsal amputation are considered an Amputation of the foot *Approved Claimants receiving points for Amputation of the foot shall receive no points pursuant to 2d to 2i	24 points
2d	Amputation of toes being amputation of all 5 toes at the metatarsophalangeal joint.	14 points
2e	Amputation of toe being amputation with loss of the distal end of the first metatarsal.	8 points
2f	Amputation of toe being bone amputation of the big toe at the metatarsophalangeal joint.	4 points
2g	Amputation of toe being amputation of the distal end of the fifth Metatarsal.	4 points
2h	Amputation of toe being amputation of the big toe at the interphalangeal joint.	4 points
2i	Amputation of toes being total or partial amputation of the second, third, fourth and fifth toes * Approved Claimants shall receive 1 point for a total or partial amputation of the second, third, fourth and fifth toes up to a maximum of 4 points	2 point
2j	Wound debridement or incision and drainage procedure following an eligible amputation procedure. Wound complications (including infection, dehiscence, wound breakdown, seroma, hematoma, osteomyelitis, tissue necrosis, or stump edema) following an eligible amputation procedure. Approved Claimants shall receive 2 points for each procedure up to a maximum of 6 points.	4 points

2l	Death resulting from lower limb amputation.	4 points
Maximum Level 2 points = 40		
Level 3 Diabetic Ketoacidosis (maximum qualifying points = 18)		
3a	Diabetic Ketoacidosis diagnosed and treated without hospital admission	14 points
3b	Diabetic Ketoacidosis requiring hospital admission.	16
3c	Death resulting from diabetic ketoacidosis.	2 points
Maximum Level 3 points = 18		
Age Adjustments **(as of the date of Eligible Injury)**		
4a	0-40 years	5 points
4b	41-50 years	4 points
4c	51-60 years	3 points
4d	61-70 years	2 points
4e	71-80 years	1 points
4f	81 + years	0 points
Hospital Duration Adjustment **Number of days hospitalized as a result of Eligible Injury**[1]		
5a	0 days	0 points
5b	1-4 days	3 points
5c	5-9 days	6 points
5d	10-14 days	9 points
5e	15 + days	12 points
Maximum Hospital During Adjustment for all Eligible Injuries = 12 points		

[1] Attribution of hospitalization to an Eligible Injury(s) is to be established by evidence of contemporaneous hospital treatment for the Eligible Injury(s). For clarity, if an Approved Claimant's hospital stay is extended after completing treatment for an Eligible Injury, such hospital time is not attributable to the Eligible Injury for the purposes of the Hospital Duration Adjustment.

Risk Factor Adjustment		
Class Members may seek a risk factor adjustment to increase their cumulative point value by fifty percent (50%) by submitting a Risk Factor Declaration.		
The existence of **<u>any</u>** of the following risk factors makes an Approved Claimant ineligible for the Risk Factor Adjustment.		
A	Smoking	Approved Claimants who smoked cigarettes or cigars within two (2) years of their Eligible Injury.
B	Alcohol Abuse	Approved Claimants diagnosed with alcoholism, alcohol dependence, or alcohol abuse, or a similar reference, within two (2) years of their Eligible Injury.
C	Multiple SGLT2 Inhibitors	Approved Claimants with usage of an additional SGLT2 inhibitor within 30 days of their Eligible Injury. For greater certainty, additional SGLT2 inhibitors are: dapagliflozin (Forxiga) and empagliflozin (Jardiance).
The existence of **<u>any</u>** of the following risk factors makes an Approved Claimant ineligible for the Risk Factor Adjustment **<u>specifically for Acute Kidney Injury claims</u>**		
D	Kidney disease	Approved Claimants who received a diagnosis of kidney disease before their Eligible Injury.
The existence of **<u>any</u>** of the following risk factors makes an Approved Claimant ineligible for the Risk Factor Adjustment **<u>specifically for Lower Limb Loss claims</u>**		
E	Peripheral vascular disease (PVD)	Approved Claimants who received a diagnosis of PVD before their Eligible Injury.
F	Diabetic neuropathy	Approved Claimants who received a diagnosis of diabetic neuropathy before their Eligible Injury.
G	Prior lower limb amputation(s)	Approved Claimants who underwent a lower limb amputation before their Eligible Injury.
H	Charcot foot	Approved Claimants who received a diagnosis of Charcot foot before their Eligible Injury.

For greater clarity, pursuant to this Compensation Protocol points are not allocated for any reason other than as provided in this section including, without limitation, derivative statutory or common law claims of family members.

12. **Excess Funds**

If six months after the payment of funds there are excess funds as a result of cheques having become stale dated and/or such other forms of payment as may be made to Approved Claimants and which may otherwise expire without having been claimed, such excess funds shall be dealt with as follows.

The Claims Administrator shall determine, in its sole discretion, if there are sufficient excess funds such that a payment can be made to Approved Claimants in an economically efficient manner. If so, such excess funds shall be paid to all Approved Claimants on a *pro rata* basis.

If the Claims Administrator determines that it is not efficient to make the *pro rata* payment or if there are still excess funds six months after the *pro rata* payment has been made and such payments are stale dated, then all excess funds shall be donated, *cy près* to an organization(s) to benefit diabetic health and research, as approved by the Court and advised by Class Counsel, subject to any amounts payable to the Fonds d'aide aux actions collective in accordance with the applicable Regulation.

Risk Factor Declaration

I,____, from the City

of_____________________________________, in the province of______________________,

SOLEMNLY DECLARE:

1. I have not smoked cigarettes or cigars within two (2) years of my Eligible Injury.

2. I have not been diagnosed with alcoholism, alcohol dependence, or alcohol abuse, or a similar reference, within two (2) years of my Eligible Injury.

3. I have not ingested additional SGLT2 inhibitors known as dapagliflozin (Forxiga) and/or empagliflozin (Jardiance) within thirty (30) days of my Eligible Injury.

4. I am making a claim for an Acute Kidney Injury under the Invokana National Settlement Agreement and prior to suffering my Eligible Injury, I was **not** diagnosed with kidney disease.
   (CROSS OUT THE ABOVE PARAGRAPH IF INAPPLICABLE)

5. I am making a claim for Lower Limb Loss under the Invokana National Settlement Agreement and prior to suffering my Eligible Injury, I was **not** diagnosed with **any** of the following:

   (i) Peripheral vascular disease;
   (ii) Diabetic neuropathy;
   (iii) who underwent a lower limb amputation before my Eligible Injury; or
   (iv) Charcot foot.

   (CROSS OUT THE ABOVE PARAGRAPH IF INAPPLICABLE)

6. I acknowledge and understand that this Risk Factor Declaration and any supporting documents will be utilized by the Claims Administrator in assigning points pursuant to the Invokana National Settlement Agreement Compensation Protocol.

7. I acknowledge that the provision of my medical records as required pursuant to the Invokana National Settlement Agreement Compensation Protocol may be reviewed by the Claims Administrator to confirm the contents of this Declaration.

8. After reviewing the information that has been supplied in this Declaration, I declare under penalty of perjury that the information provided in this Declaration is true and correct to the best of my knowledge, information and belief.

9. I hereby consent to the disclosure of the information contained herein to the extent necessary to process my claim. I hereby authorize the Claims Administrator to contact me as required in order to administer the claim.

Date: ____

Claimant's Signature (or Claimant's Representative)

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Printed Name of Claimant (or Claimant's Representative)

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Date: Signature of Witness

____

Printed Name of Witness