

**Claim Form must be submitted electronically in the on-line claims administration portal at <https://portal.invokanacanadasettlement.com>,  
by the Claims Bar Deadline of August 14, 2023 11:59 PM EST**

## **INVOKANA NATIONAL SETTLEMENT AGREEMENT CLAIM FORM**

ESTATE OF RAYMOND DUCK

**Plaintiffs**

- and -

JANSSEN INC., JANSSEN  
PHARMACEUTICALS INC., JOHNSON  
& JOHNSON, AND JOHNSON &  
JOHNSON INC.

**Defendants**

PROVINCE OF ONTARIO  
Ontario Superior Court of Justice  
Court File No.: No.CV-18-00000570-  
00CP

STEVEN VARNAI & JOANNE GIROUX

**Plaintiffs**

v.

JANSSEN INC., JANSSEN  
PHARMACEUTICALS INC., JOHNSON  
& JOHNSON, AND JOHNSON &  
JOHNSON INC.

**Defendants**

PROVINCE OF QUEBEC  
Superior court of Quebec  
District of Montreal  
(Class Actions)  
No.: 500-06-000906-186

RONALD ALLEN FIDDLER

**Plaintiffs**

- and -

JANSSEN INC., JANSSEN  
PHARMACEUTICALS INC., JANSSEN  
ORTHO LLC, JOHNSON & JOHNSON,  
and JOHNSON & JOHNSON INC.,

**Defendants**

PROVINCE OF SASKATCHEWAN  
Court of Kings's Bench for Saskatchewan  
Judicial Centre of Regina  
Q.B.G. 2809/2015

### **Trilogy Class Action Services**

#### **Invokana National Settlement Agreement**

117 Queen Street, P.O. Box 1000,  
Niagara-on-the-Lake, Ontario, L0S 1J0

**Phone:** 1-877-400-1211

**Fax:** 1-416-342-1761

**Email:** [claims@trilogyclassactions.ca](mailto:claims@trilogyclassactions.ca)

### **Websites**

**English:** <https://www.invokanacanadasettlement.com>

**French:** <https://fr.invokanacanadasettlement.com>

**Portal:** <https://portal.invokanacanadasettlement.com>

## Invokana National Settlement Agreement CLAIM FORM INSTRUCTIONS

**Failure to fully comply with these instructions may result in the Rejection of your Claim Form.**

To register as a Settling Claimant and submit your Claim Form with supporting documentation electronically in the online claims administrator portal, click here: <https://portal.invokanacanadasettlement.com>.

Your Claim Form must be submitted electronically.

*The enclosed instructions, information and key defined terms are pursuant to the Court approved Settlement Agreement and Compensation Protocol. If you wish to review the entire Settlement Agreement and Compensation Protocol, please see the public documents section in the portal or visit the class action designated website at:*

<https://www.invokanacanadasettlement.com/case-documents>

### **Key Defined Terms - Pursuant to the Court approved Compensation Protocol**

**“Approved Claimant”** means a Settling Claimant that the Claims Administrator determines is eligible for compensation under the Compensation Protocol;

**“Claims Administrator”** means the firm proposed by Class Counsel and appointed by the Courts to administer the Settlement Amount in accordance with the provisions of this Settlement Agreement and the Compensation Protocol, and any employees of such firm;

**“Claim Form”** means the claim form developed by the Claims Administrator in consultation with Class Counsel and approved by the Court;

**“Classes”** means the Ontario Class, Saskatchewan Class, and Quebec Class;

**“Compensation Protocol”** means the Court-approved plan for administering this Settlement Agreement and distributing the Settlement Amount to Class Members;

**“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;

**“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.

**“Invokana Product(s)”** means Invokana, Invokamet, and/or Invokamet XL;

**“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.

**“Ontario Class”** means:

- (i) All persons resident in Canada (at the time of the certification order), with exception of Saskatchewan Class Members and Quebec Class Members, who were prescribed and used Invokana, Invokamet, and/or Invokamet XR in Canada at any time on or before the date of the certification order; and
- (ii) All persons, with exception of Saskatchewan Class Members and Quebec Class Members, who by virtue of a personal relationship to one or more of such persons described in (i) above have claims for common law or statutory damages;

**“Quebec Class”** means:

- (i) All persons resident in Quebec (at the time of the authorization) who were prescribed and used Invokana, Invokamet, and/or Invokamet XR in Quebec at any time on or before the date of the certification order; and
- (ii) All persons, who by virtue of a personal relationship to one or more of such persons described in (i) above have claims for common law or statutory damages;

**“Saskatchewan Class”** means:

- (i) All persons resident in Saskatchewan (at the time of the certification order) who were prescribed and used Invokana, Invokamet, and/or Invokamet XR in Saskatchewan at any time on or before the date of the certification order; and
- (ii) All persons who by virtue of a personal relationship to one or more of such persons described in (i) above have claims for common law or statutory damages;

**“Referee”** means the person, selected by Class Counsel and approved by the Court, that will hear appeals from decisions of the Claims Administrator;

**“Settling Claimant”** (collectively, the “Settling Claimants”) means each Class Member who files a claim pursuant to the Compensation Protocol;

## **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.

## **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".

**Claim Form must be submitted electronically in the on-line claims administration portal at <https://portal.invokanacanadasettlement.com>, by the Claims Bar Deadline of August 14, 2023, 2023 11:59 PM EST.**

## INVOKANA NATIONAL SETTLEMENT AGREEMENT CLAIM FORM

### SETTLING CLAIMANT IDENTIFICATION

Name and Contact Details of the Party Who is Claiming:

First Name:	Middle Name:	Last Name:
Street Address:	Country:	
City or Town:	Province:	Postal Code:
Home Number: Area Code	Number	Email Address:
Language Preference: <input type="checkbox"/> English <input type="checkbox"/> French		

If you are Claiming on behalf of a Person, name of the Person you are claiming on behalf of or the name of the Insured Person:

First Name:	Middle Name:	Last Name:
Street Address:	Country:	
City or Town:	Province:	Postal Code:
Home Number: Area Code	Number	Email Address:
Language Preference: <input type="checkbox"/> English <input type="checkbox"/> French		Relationship to the Person:

## **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.

## **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.

## **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.

**\*For a complete breakdown of the Allocation of Points, please refer to page 4 of the Compensation Protocol found at [www.invokanacanasettlement.com/case-documents](http://www.invokanacanasettlement.com/case-documents).**

## **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.

<b>CLAIMANT ELIGIBILITY</b>		
Province or Territory of Residence as of DATE OF CERTIFICATION:		
I/the Patient was prescribed and used Invokana, Invokamet, and/or Invokamet XR at any time on or before DATE OF CERTIFICATION and subsequently experienced acute kidney injury, diabetic ketoacidosis or lower limb loss: (Yes or No)		
Date of first use of the medication:	received as treatment in hospital;	
	received as treatment in doctor's office; or	
	after filling a prescription.	
Date of Birth:		
<b>SUPPORTING DOCUMENTATION REQUIRED FOR CONFIRMATION</b>		

<b>ELIGIBLE INJURY - ACUTE KIDNEY INJURY - Diagnosed on or before April 25, 2016</b>		
1a	Did you or the patient suffer Acute Kidney Injury?	
1b	Did you or the patient have Renal Replacement Therapy (continuous hemofiltration, hemodialysis, intermittent hemodialysis, or peritoneal dialysis)?	
1c	Was there Prolonged Renal Replacement Therapy? (lasting 6 or more months)	
1d	Did death occur as a result from Acute Kidney Injury or Acute Renal Failure?	
Age at which Injury occurred.		0-40 years
		41-50 years
		51-60 years
		61-70 years
		71-80 years
		81+ years
Number of days hospitalized as a result of Injury.		0 days
		1-4 days
		5-9 days
		10-14 days
		15+ days
<b>SUPPORTING DOCUMENTATION REQUIRED FOR CONFIRMATION</b>		

<b>ELIGIBLE INJURY - LOWER LIMB LOSS - Occurring on or before December 6, 2017</b>		
2a	<p>Was there amputation of the leg above the knee?</p> <ul style="list-style-type: none"> <li>Approved Claimants receiving points for amputation of leg above knee shall receive no points pursuant to 2b to 2i</li> </ul>	
2b	<p>Was there an amputation of leg below the knee?</p> <ul style="list-style-type: none"> <li>Approved Claimants receiving points for amputation of leg below the knee shall receive no points pursuant to 2a or 2c to 2i</li> </ul>	
2c	<p>Was there an amputation of the foot?</p> <ul style="list-style-type: none"> <li>Amputation at the ankle – aka Symes amputation</li> <li>Midtarsal amputation – aka Chopart amputation</li> <li>Tarsometatarsal amputation – aka Lisfranc amputation</li> </ul> <p>Trans-metatarsal amputation are considered an amputation of the foot.</p> <ul style="list-style-type: none"> <li>Approved Claimants receiving points for Amputation of the foot shall receive no points pursuant to 2d to 2i</li> </ul>	
2d	<p>Was there an amputation toes – being an amputation of all 5 toes at the metatarsophalangeal joint?</p>	
2e	<p>Was there an amputation of toe being amputation with loss of the distal end of the first metatarsal?</p>	
2f	<p>Was there amputation of toe being bone amputation of the big toe at the metatarsophalangeal joint?</p>	
2g	<p>Was there amputation of toe being amputation of the distal end of the fifth Metatarsal?</p>	
2h	<p>Was there amputation of toe being amputation of the big toe at the interphalangeal joint?</p>	
2i	<p>Was there amputation of toes being total or partial amputation of the second, third, fourth and fifth toes?</p> <ul style="list-style-type: none"> <li>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.</li> </ul>	
2j	<p>Was there wound debridement or incision and drainage procedure following an eligible amputation procedure.</p> <p>Was there wound complications (including infection, dehiscence, wound breakdown, seroma, hematoma, osteomyelitis, tissue necrosis, or stump edema) following an eligible amputation procedure.</p> <p>Approved Claimants shall receive 2 points for each procedure up to a maximum of 6 points.</p>	
2l	<p>Did death occur as a result from lower limb amputation?</p>	
Age at which Injury occurred.		0-40 years
		41-50 years



	51-60 years	
	61-70 years	
	71-80 years	
	81+ years	
Number of days hospitalized as a result of Injury.	0 days	
	1-4 days	
	5-9 days	
	10-14 days	
	15+ days	

**SUPPORTING DOCUMENTATION REQUIRED FOR CONFIRMATION**

**ELIGIBLE INJURY - DIABETIC KETOACIDOSIS - Maximum 23 points  
Diagnosed on or before August 31, 2016**

3a	Were you or the patient diagnosed with Diabetic Ketoacidosis and treated without hospital admission?	
3b	Were you or the patient diagnosed with Diabetic Ketoacidosis requiring hospital admission?	
3c	Did death occur as a result of Diabetic Ketoacidosis?	

Age at which Injury occurred.	0-40 years	
	41-50 years	
	51-60 years	
	61-70 years	
	71-80 years	
	81+ years	

Number of days hospitalized as a result of Injury.	0 days	
	1-4 days	
	5-9 days	
	10-14 days	
	15+ days	

**SUPPORTING DOCUMENTATION REQUIRED**

**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.

\_\_\_\_\_  
Settling Claimant's Signature  
(or Claimant Representative)

\_\_\_\_\_  
Printed Name of Settling Claimant  
(or Claimant Representative)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Printed Name of Witness

\_\_\_\_\_  
Date