SPECIAL AUTHORIZATION REQUEST

CROHN'S DISEASE

Fax requests to (902) 368-4905, email to drugprograms@gov.pe.ca **OR** mail requests to PEI Pharmacare, P.O. Box 2000, Charlottetown, PE, C1A 7N8
HIGH COST DRUG PROGRAM PATIENT APPLICATION ALSO REQUIRED PRIOR TO COVERAGE

SECTION 1 – PRESCRIBER INFORMATION

SECTION 2 – PATIENT INFORMATION

NAME AND MAILING ADDRESS	PATIENT (FAMILY NAME)	PATIENT (GIVEN NAME)
	DATE OF BIRTH (YYYY/MM/DD)	PERSONAL HEALTH NUMBER (PHN)
PHONE NUMBER (INCLUDE AREA CODE):	PATIENT'S MAILING ADDRESS	
FAX NUMBER (INCLUDE AREA CODE):		

SECTION 3 – MEDICATION AND DETAIL INFORMATION

REQUESTED DRUG AND MEDICAL CONDITION (PLEASE CHECK ONE CONDITION AND DRUG) Approval will NOT be considered in combination with other biologic agents.	PATIENT WEIGHT (kg)

☐ **MODERATE TO SEVERE ACTIVE CROHN'S DISEASE**

- ☐ **Adalimumab** – Initial 12 week approval is for an induction dose of 160 mg followed by 80 mg 2 weeks later, then 40 mg every 2 weeks thereafter.
- ☐ **Infliximab** – Initial approval is for 3 doses of 5 mg/kg/dose administered at 0, 2 and 6 weeks.
- ☐ **Risankizumab** – Initial approval for IV doses of 600mg at 0, 4 and 8 weeks.
- ☐ **Upadacitinib –** Initial 16 week approval is for 45 mg daily for 12 weeks, followed by a maximum of 30 mg daily thereafter
- ☐ **Ustekinumab** – Initial 16 week approval is for a single IV dose of up to 520 mg at week 0 and a subcutaneous dose of 90 mg at week 8 and 16
- ☐ **Vedolizumab** – Initial approval is for 300 mg administered at 0, 2 and 6 weeks.

MODERATE TO SEVERE CROHN'S CRITERIA - CHECK/FILL OUT RELEVANT BOXES BELOW

☐ **Patient has moderate to severe active Crohn's Disease and is refractory to, intolerant of, or has contraindications to:**

☐ **Prednisone 40mg (or equivalent) daily ≥ 2 weeks**

DRUG	DOSE	DURATION OF TREATMENT
If intolerance or contraindicated, please describe:		

AND

☐ **Azathioprine ≥ 2mg/kg/day for ≥ 3 months**

DRUG	DOSE	DURATION OF TREATMENT
If intolerance or contraindicated, please describe:		

OR

☐ **Mercaptopurine ≥ 1mg/kg/day for ≥ 3 months**

DRUG	DOSE	DURATION OF TREATMENT
If intolerance or contraindicated, please describe:		

OR

☐ **Methotrexate (SC or IM) ≥ 15mg/week for ≥ 3 months**

DRUG	DOSE	DURATION OF TREATMENT
If intolerance or contraindicated, please describe:		

SECTION 3 CONTINUED – MEDICATION AND DETAIL INFORMATION

☐ **FISTULIZING CROHN'S DISEASE**

☐ **Infliximab** – Initial approval is for 3 doses of 5 mg/kg/dose administered at 0, 2 and 6 weeks.

FISTULIZING CROHN'S CRITERIA - CHECK/FILL OUT RELEVANT BOXES BELOW

☐ **Patient has Fistulizing Crohn's Disease with a Harvey Bradshaw Index score of 7 or more**

AND

☐ **Patient has actively draining perianal or enterocutaneous fistula(e) that have recurred or persisted despite a course of appropriate antibiotic therapy (e.g. ciprofloxacin with or without metronidazole for a minimum of 3 weeks**

DRUG	DOSE	DURATION OF TREATMENT

AND

☐ **Patient has not responded to immunosuppressive therapy (azathioprine, mercaptopurine or methotrexate)**

DRUG	DOSE	DURATION OF TREATMENT

OR

☐ **Treatment discontinued due to serious adverse reactions**

REACTION	DRUG	DOSE	DURATION OF TREATMENT

OR

☐ **Contraindication to use of immunosuppressive therapy**

CONTRAINDICATION

SECTION 4 – CONTINUED COVERAGE

Coverage will be for a maximum of 12 months, except for **biosimilars***, which will be set up for long term coverage.

Renewal of coverage will require confirmation of continued response._____

☐ **Adalimumab*** continued coverage will be limited to 40 mg every 2 weeks
☐ **Infliximab*** continued coverage will be limited to 5 mg/kg/dose every 8 weeks
☐ **Risankizumab** continued coverage will be limited to 360mg subcutaneously at Week 12, and every 8 weeks thereafter
☐ **Upadacitinib** continued coverage will be limited to 30 mg daily
☐ **Ustekinumab*** continued coverage will be limited to 90 mg subcutaneously every 8 weeks
☐ **Vedolizumab** continued coverage will be limited to 300 mg every 8 weeks

Patient's weight (kg) :_____

Special Authorization grants coverage to a drug that otherwise would not be eligible for coverage. Coverage is provided to patients in specific medical circumstances as defined in the PEI Pharmacare Formulary and **subject to Pharmacare Drug Program plan rules, including deductible and eligibility requirements.**

PEI Pharmacare may request additional documentation to support this Special Authorization Request. Personal information on this form is collected under section 31(c) of Prince Edward Island's Freedom of Information & Protection of Privacy (FOIPP) Act as it relates directly to and is necessary for providing services under the PEI High-Cost Drug Program.

If you have any questions about this collection of personal information, you may contact the program office at 902-368-4947 or at the address at the top of the form.

PRESCRIBER SIGNATURE (REQUIRED) **DATE**