CELLTRION CONNECT™
PATIENT SUPPORT PROGRAM

SEND COMPLETED ENROLMENT FORM TO:

1-855-966-2223 | support@celltrionconnect.ca | Questions? 1-855-966-1648

Pr Remdantry™ IV Infliximab
Constant. Confidence. Control.

Pr Remsima™ SC Infliximab

The CELLTRION CONNECT™ Patient Support Program (the "Program") is sponsored and offered by Celltrion Healthcare Canada Limited ("Celltrion") in conjunction with its third-party providers ("Program Administrators"), to support patients who have been prescribed Remdantry™ IV or Remsima™ SC ("Support Services"). Information contained in this document is used by the Program to facilitate access to Remdantry™ IV or Remsima™ SC.

PATIENT INFORMATION

First name: _____ Last name: _____ Date of birth: _____ Female ☐ Male ☐ Non-binary ☐

Address: _____ Email: _____

Cellphone: _____ Okay to leave message: Yes ☐ No ☐ Best time to be contacted: AM ☐ PM ☐

Tel. (home): _____ Known allergies: Yes ☐ No ☐ If yes, please specify: _____

Preferred language: English ☐ French ☐ Other ☐ Please specify: _____ Personal health number (PHN): _____

FOR MINOR PATIENT

_____ Legal guardian name

_____ Relationship to patient

PHYSICIAN INFORMATION

Name: _____

Specialty: _____

License number: _____

Office contact name: _____

Address: _____

Tel (office): _____ Fax (office): _____

Email: _____

PHARMACY

Do you have a preferred pharmacy that you are working with? Yes ☑ No ☐

Pharmacy name: **BioPro Biologics Pharmacy**

Address: **845 W Broadway Vancouver, BC, V5Z 1J9**

Tel: **778-379-8161**

Fax: **778-379-8160**

Preferred infusion clinic: MedInfuse Clinic Tel: 778-381-5883 Fax: 778-897-3223

PHYSICIAN PRESCRIBING SECTION FOR REMDANTRY™ IV

Refer to the recommended dosing on page 2. Please ☑ and complete the required information.

☐ Patient is already on infliximab ☐ Patient is new to infliximab

Patient weight (kg): _____ Date of weight: _____ Dose: _____ mg Provincial formulary code (if applicable): _____

DIAGNOSIS: ADULT ☐ Crohn's Disease (CD) ☐ Fistulising Crohn's Disease (FCD) ☐ Ankylosing Spondylitis (AS) ☐ Plaque Psoriasis (PsO)
☐ Ulcerative Colitis (UC) ☐ Rheumatoid Arthritis (RA) ☐ Psoriatic Arthritis (PsA)

PEDIATRIC ☐ Ulcerative Colitis (UC) (≥6 years of age) ☐ Crohn's Disease (CD) (≥9 years of age)

FREQUENCY/DURATION Requested start date:* _____ ☐ Induction: Week ☐ 0 ☐ 2 ☐ 6

☐ Maintenance: Every ____ weeks for ____ months. Repeat: x ____. ☐ Administer Remdantry™ IV dose by IV infusion using infusion clinic standard Remdantry™ IV protocol.

☐ 1-hour infusion: If my rheumatoid arthritis, Crohn's disease (pediatric or adult), or ulcerative colitis (pediatric or adult) patient has received and tolerated the last three 2-hour infusions, initiate the following order: utilize the current shortened infusion recommended standard protocol to infuse Remdantry™ IV over no less than 1 hour, or as tolerated, and manage infusion reactions as applicable.

*The infusion solution must be administered over a period of not less than 2 hours unless a 1-hour infusion is prescribed considering the conditions listed above. Emergency equipment, such as adrenaline, antihistamines, corticosteroids and an artificial airway must be available.

PHYSICIAN PRESCRIBING SECTION FOR REMSIMA™ SC

Refer to the recommended dosing on page 2. Requested start date: _____ Please ☑ and complete the required information.

DIAGNOSIS: ☐ Crohn's Disease (CD) ☐ Ulcerative Colitis (UC) ☐ Rheumatoid Arthritis (RA)

Drug: Remsima™ SC (infliximab subcutaneous)

☐ Autoinjector: (DIN: 02511584) Dose: 120 mg SC Frequency: ☐ Inject every 2 weeks Duration: _____ Refills: _____ Other: _____

For patients transitioning from IV infliximab to Remsima™ SC, indicate date of last infusion: _____

☐ **Dose induction required**

Drug: ☐ Remsima™ SC 120 mg OR ☐ Intravenous infliximab Brand: _____ Patient weight: _____ Date of weight: _____

Dose (mg): Exact dose: __ OR Exact # of vials: ___ 100 mg vials

Frequency/duration **SC induction weeks:** ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 (RA only) **IV Induction weeks:** ☐ 0 ☐ 2 ☐ 6

☐ Other dosing instructions: _____ Preferred infusion clinic: _____

For infusion reaction management: follow the current recommended standard protocol.

List any required pre-medications: _____

VACCINE AND TUBERCULOSIS (TB) ASSESSMENT

TB test ☐ TB Skin Test ☐ QuantiFERON TB Gold Test ☐ Not required
☐ Positive (+) Date: _____ ☐ Negative (-) Date: _____

Chest x-ray ☐ Not required ☐ Completed results Date: _____

Shingles vaccine ☐ Required Brand: _____ # of doses: ____

Pneumococcal vaccine ☐ Required Brand: _____ # of doses: ____

Relevant medical history/notes: _____

OPTIONAL TESTING SERVICES (PLEASE ☑ ALL THAT APPLY)

☐ **Therapeutic Drug Monitoring (trough)**
- ☐ At baseline, before the switch: ___
- ☐ At third SC dose
- ☐ At week __ ☐ At dose __
- ☐ Repeat in ____weeks
- ☐ Repeat in ____months
- ☐ ASAP: _____

☐ **Antidrug Antibody Testing**
- ☐ ASAP: _____

Calprotectin Testing
- ☐ IBDoc®

OR
- ☐ QuantOn Cal®
- ☐ At baseline: _____
- ☐ Repeat in __weeks
- ☐ Repeat in __months

My signature acknowledges that:

- The above prescription parameters comply with the indications set forth in the Product Monograph.
- I consent to the patient being enrolled in the CELLTRION CONNECT™ Patient Support Program (the "Program").
- I have the patient's consent to share the patient's information in this form with the Program and as needed, to provide the Program's services.
- I consent to Celltrion contacting me with respect to the enrolment of this patient as may be required to administer or deliver the Program or the Support Services, or in the event of an adverse drug event relating to Remdantry™ IV or Remsima™ SC. This prescription is the original prescription that will be sent to the pharmacy chosen by the patient.
- I consent to the Program Administrator or designated agent to forward the prescription to the Program and to the pharmacy as required.
- I consent to the Program Administrator collecting, using and disclosing my information for the purpose of delivering the Support Services, or for contacting me to improve the quality of the Support Services offered under the Program.

Physician name _____

Physician signature _____

Date‡ _____

‡Effective date.
IV: Intravenous; SC: Subcutaneous.

RECOMMENDED DOSE FOR REMDANTRY™ IV*

Crohn's Disease (Adults and Pediatrics ≥9 years of age)
5 mg/kg IV induction at weeks 0, 2 and 6, followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter

Ulcerative Colitis (Adults and Pediatrics ≥6 years of age)
5 mg/kg IV induction at weeks 0, 2 and 6, followed by 5 mg/kg every 8 weeks thereafter

Fistulising Crohn's Disease
5 mg/kg IV induction regimen at weeks 0, 2 and 6, followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter

Rheumatoid Arthritis
3 mg/kg IV followed by additional 3 mg/kg doses at weeks 2 and 6 after the first infusion, then every 8 weeks thereafter. Give in combination with methotrexate

Ankylosing Spondylitis
5 mg/kg IV followed by additional 5 mg/kg doses at weeks 2 and 6 after the first infusion, then every 6 to 8 weeks thereafter

Psoriatic Arthritis
5 mg/kg IV followed by additional similar doses at weeks 2 and 6 after the first infusion then every 8 weeks thereafter. Use with or without methotrexate

Plaque Psoriasis
5 mg/kg IV followed by additional 5 mg/kg doses at weeks 2 and 6 after the first infusion, then every 8 weeks thereafter

*See Product Monograph for recommended dose adjustments

RECOMMENDED DOSE FOR REMSIMA™ SC

Ulcerative Colitis and Crohn's Disease

- Maintenance dosing of Remsima™ SC 120 mg once every 2 weeks starts 4 weeks following completion of an induction regimen with infliximab IV infusion

OR

- When switching from maintenance therapy of IV infliximab to Remsima™ SC, Remsima™ SC may be administered 8 weeks after the last infliximab IV infusion

Rheumatoid Arthritis

- SC induction with Remsima™ SC 120 mg at Week 0, followed by additional SC injections at 1, 2, 3 and 4 weeks after first injection, then once every 2 weeks, starting from Week 6

OR

- IV induction with 3 mg/kg dose of IV infliximab at Weeks 0 and 2, followed by Remsima™ SC maintenance with the 120 mg dose once every 2 weeks, starting from Week 6
- When switching from maintenance therapy of IV infliximab to Remsima™ SC, Remsima™ SC may be administered 8 weeks after the last infliximab IV infusion

NOTES

Preferred Pharmacy: BioPro Biologics Pharmacy (Tel: 778-379-8161 Fax: 778-379-8160)

Preferred Infusion Clinic: MedInfuse Clinic (Tel: 778-381-5883 Fax: 778-897-3223)

PATIENT CONSENT

The CELLTRION CONNECT™ Patient Support Program (the "**Program**") is designed to support patients in Canada who have been prescribed a Celltrion product. Celltrion administers this Program via third-party service providers appointed by Celltrion ("**Program Administrators**"), and offers various support services for individuals. Depending on eligibility, these services may include education and training, product information, insurance reimbursement assistance, treatment services, or financial assistance (collectively called "**Support Services**").

Any information collected and shared to administer the Support Services may include personally identifiable information ("**Personal Information**") about me. This includes my contact information, date of birth, sensitive health information (such as medical conditions, treatments, care management, health insurance, and prescription details), and any other information disclosed in connection with the Support Services.

I understand and agree that the Program does not provide medical advice or replace the need for me to speak with my treating healthcare provider for medical-related inquiries. I also recognize that my participation in the Program is voluntary.

I understand that Program Administrator employees and/or agents will handle my Personal Information to provide Support Services. This information will be processed in accordance with privacy laws and Celltrion's privacy/data protection standards (available at https://www.celltrionhealthcare.ca/contactus/law/).

I agree to Celltrion and the Program Administrators collecting information from and sharing information with my healthcare providers and their staff, pharmacies, pharmacists, insurance companies, provincial public payers, or other healthcare and service providers (collectively referred to as "**Providers**") as necessary to provide me with the Support Services. Celltrion will not use or share my Personal Information for any purpose other than for the Program, unless required or permitted by law.

The Program Administrators may anonymize and aggregate my Personal Information with that of other patients and provide it to Celltrion and its service providers for the purposes of reporting, assessing, auditing, monitoring, improving, or evaluating the Program for the benefit of patients. My anonymized statistical and aggregated information may also be collected, shared, and published with healthcare providers and third parties for reimbursement, publication, or commercial purposes.

I agree to be contacted by the Program Administrators through various means (e.g., phone, fax, email, mail, SMS/text message, etc.) to coordinate Program services or inquire about my experience with the Program to improve the Support Services.

I agree that my de-identified Personal Information may be shared with Celltrion and my Providers for the purpose of reporting adverse events (side effects). Such information may be provided to Health Canada or to another regulatory agency to report any adverse drug events or as otherwise required by law.

I understand that my Personal Information may be stored or processed outside of Canada. If this is the case, then my information would be subject to the laws of the country where it is stored. That country may have laws that require my Personal Information be disclosed to the government under different circumstances than would Canada.

I understand and agree that Celltrion has the right without notice to (1) make changes to the scope of Support Services offered; (2) make changes to the eligibility requirements for the Support Services; or (3) discontinue the Program or any of the Support Services. If at any time Celltrion appoints a new Program Administrator, I will be notified of same and I hereby authorize Celltrion to transfer my Personal Information to the new Program Administrator for the purposes of continuing my participation in the Program. I understand that I have the right to have access to or to correct my Personal Information held by Program Administrators by contacting the Program at support@celltrionconnect.ca, or by telephone at: 1-855-966-1648. I understand that I have the right at any time to withdraw my consent to the use of my Personal Information but if I do decide to do so, I will no longer be participating in the Program or have access to the services.

In signing this form, I consent to the above.

☐ In addition to the above consent, I agree to the Program Administrator contacting me by electronic or other means for the purposes of market research. I acknowledge that I may at any time opt-out from such communications by advising Program Administrator by email at: support@celltrionconnect.ca.

Patient name (please print) _____ Patient signature _____ Date _____

For more information, please refer to the Remdantry™ IV and Remsima™ SC Product Monographs.
The Product Monographs are available upon request or they can be accessed at https://health-products.canada.ca/dpd-bdpp/search.

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