Caroline Family Health Team

Medical Directive

Title: Isotretinoin Therapy (Pharmacist)

Number: C-FHT7
Activation Date: *Review due by:*

Sponsoring/Contact Person(s): ***Kathleen Whittaker, Executive Director***
(Name, position, contact particulars) *905.632.8007 ext 108*
kathleen.w@carolinefht.ca

Order and/or Delegated Procedure:	**Appendix Attached:** ☐ **Yes** ☒ **No** **Title:**
The clinical pharmacist (RPh) may prescribe isotretinoin and order relevent laboratory investigations to monitor therapy for select patients within the Caroline Family Health Team (C-FHT)	
Recipient Patients:	**Appendix Attached:** ☒ **Yes** ☐ **No** **Title:** Appendix 1: Authorizer Approval Form
1) All patients 12 years and older and; 2) Rostered to C-FHT physicians who have signed the attached authorizer approval form (Appendix 1)	
Authorized Implementers:	**Appendix Attached:** ☒ **Yes** ☐ **No** **Title:** Appendix 2: Implementer Approval Form
Authorized to C-FHT clinical pharmacist (RPh) (Appendix 2)	
Indications:	**Appendix Attached:** ☐ **Yes** ☒ **No** **Title:**
1) Severe nodular and/or inflammatory acne 2) Acne conglobata 3) Recalcitrant acne	
Contraindications: 1) Pregnancy 2) Breastfeeding women 3) Hepatic and renal insufficiency 4) Hypervitaminosis A 5) Patients with excessively elevated blood lipid values 6) Patients taking concurrent tetracyclines 7) Patients who are sensitive to isotretinoin or to any of the excipients	
Consent:	**Appendix Attached:** ☒ **Yes** ☐ **No** **Title:** Appendix 3: Informed Consent Form
The clinical pharmacist (RPh) will obtain written informed consent from the patient or substitute decision maker using the standardized Informed Consent Form for Accutane (Isotretinoin).	
Guidelines for Implementing the Order/Procedure:	**Appendix Attached:** ☒ **Yes** ☐ **No** **Title:** Appendix 3: Informed Consent Form Appendix 4: Pregnancy Prevention Checklist Appendix 5: Psychiatric Assessment Checklist

1) Pre-Isotretinoin Assessment - RPh will review information on isotretinoin including but not limited to the following: indication, dosing, side-effects, monitoring, commitment to monthly blood work, pregnancy prevention (if applicable). Written informed consent will be obtained from the patient or legal substitute decision maker (Appendix 3). A pregnancy prevention checklist will be completed if applicable (Appendix 4). A baseline patient health questionnaire-9 (PHQ-9) will be completed as part of the psychiatric assessment checklist (Appendix 5). RPh will order the folllowing baseline laboratory investigations: blood glucose, serum creatinine, complete blood count, lipid profile (total cholesterol, triglycerides, HDL, LDL, non-HDL), ALT, ALP, serum HCG (for all females). For female patients, two negative serum pregnancy tests must be documented prior to starting isotretinoin. The second pregnancy test must be within 11 days prior to starting isotretinoin.
2) Isotretinoin Initiation - RPh may prescribe isotretinoin according to dosing guidelines outlined in the isotretinoin product monograph. The patient's weight will be measured and used to calculate the isotretinoin dosage. Each prescription is limited to a maximum of 30 days to ensure ongoing patient follow up and monitoring.
3) Ongoing Monitoring of Therapy - RPh will order montly bloodwork for the following: complete blood count, lipid profile (total cholesterol, triglycerides, HDL, LDL, non-HDL), ALT, ALP, serum HCG (for all females). RPh will adjust the dosage of isotretinoin as necessary based on efficacy and safety parameters.

Documentation and Communication:	**Appendix Attached:** ☒ **Yes** ☐ **No** **Title:** Appendix 3: Informed Consent Form Appendix 4: Pregnancy Prevention Checklist Appendix 5: Psychiatric Assessment Checklist

1) Documententation in the patient's medical record as a progress note to indicate pharmacist assessment and plan for isotretinoin therapy.
2) Written informed consent, pregnancy prevention checklist and psychiatric assessment checklist to be documented in the chart prior to starting isotretinoin.
3) Verbal or written communication to physician regarding isotretinoin plan.

Review and Quality Monitoring Guidelines:	**Appendix Attached:** ☐ **Yes** ☒ **No** **Title:**

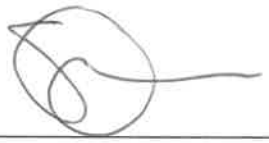
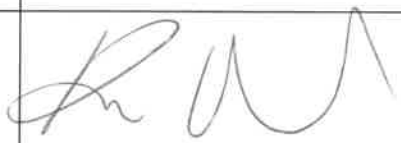
1) Annual routine review by at least one member of medical directive authorizer, one member of implementer and Executive Director.
2) Any staff member who identifies any inappropriate, untoward or unanticipated outcomes resulting from this medical directive implementation will immediately notify the most reponsible physician and his/her program manager. The program manager, in collaboration with the sponsoring physician, will immediately trigger an ad hoc review

Approving Physician(s)/Authorizer(s):	**Appendix Attached:** ☒ **Yes** ☐ **No** **Title:** Appendix 1: Authorizer Approval Form

C-FHT Authorizer Approval Form (Appendix 1)

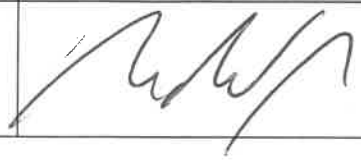
Appendix 1: Authorizer Approval Form

Title: Isotretinoin Therapy (Pharmacist)
Number: C-FHT07

Name of Authorizer	Signature	Date
Dr. Lori Chalklin		9/13/2019
Dr. Stephen Duncan		9/13/2019
Dr. Alicia Gallacio		9/13/2019
Dr. Dana Pintea		5/11/2019
Dr. Helena Liu		Sept 18, 2019
Dr. Robert Tohn		9/13/2019
Dr. David Wallik		26/9/19
Dr. Kim Walsh		9/13/2019
Dr. Chris Williams		9/13/2019

Appendix 2: Implementer Approval Form

Title: Isotretinoin Therapy (Pharmacist)
Number: C-FHT07

Name of Implementer	Signature	Date
Michael Pe, RPh		Sept 13, 2019

Appendix 3: Informed Consent Form

Title: Isotretinoin Therapy (Pharmacist)

Number: C-FHT07

Informed Consent Form

This consent form has two parts. Part I is for all patients (male and female). Part II is only for female patients.

Sign this form only if you understand all the information you have received from your physician about ACCUTANE™ ROCHE® (isotretinoin) (to be retained in physician's office).

PART I: FOR ALL PATIENTS (MALE AND FEMALE)

I have reviewed the information regarding ACCUTANE and listened to my physician and I understand the following:

- ACCUTANE is a medicine used to treat severe acne that cannot be cleared up by other acne treatments including antibiotics. My physician has told me about my choices in treating my acne.
- Serious side effects may happen while I am taking ACCUTANE. These have been explained to me. These side effects include severe birth defects in babies of pregnant females if ACCUTANE is taken during pregnancy. [Female patients must complete Part II of this form.]
- Some patients taking ACCUTANE have become depressed or experienced other mental changes such as feelings of sadness, irritability, unusual tiredness, trouble concentrating, loss of interest in usual activities, withdrawal from family and friends and loss of appetite. Some patients taking ACCUTANE have had thoughts of hurting themselves or ending their lives, tried to end their own lives, or ended their own lives. There have been reports of patients on ACCUTANE becoming aggressive or violent. No one knows if ACCUTANE caused these behaviours or if they would have happened even if the person did not take ACCUTANE. **I must tell my physician immediately if I have such feelings or thoughts.**
- I must tell my physician, before I start ACCUTANE, if I, or any member of my family, has ever had symptoms of depression, any other mental illnesses or attempted suicide, or taken medicine for any of these problems.
- I must return to see my physician as scheduled (every month) to get a new prescription for ACCUTANE and monitor my body's response to ACCUTANE.

I acknowledge that all the above points have been fully explained to me by my physician and that I clearly understand these points and the information on ACCUTANE provided to me.

Patient, Parent or Guardian Signature _____

Address _____ Telephone # _____

Physician Name _____ Date _____

PART II: ONLY FOR FEMALE PATIENTS

I have reviewed the information on ACCUTANE and listened to my physician and I understand the following:

- ACCUTANE can cause severe birth defects in babies of pregnant females if ACCUTANE is taken during pregnancy.
- I must not take ACCUTANE if I am pregnant or may become pregnant during treatment or up to one month after treatment. I am not pregnant now and do not plan to become pregnant during treatment with ACCUTANE or up to one month after stopping ACCUTANE.
- I must have two pregnancy tests prior to starting ACCUTANE and I must wait until the second or third day of my next normal menstrual period before starting ACCUTANE. If my menstrual period is abnormal in length and intensity, I should first contact my doctor.
- I must return to see my physician as scheduled for monthly pregnancy tests.
- I must use effective birth control for at least one month before starting ACCUTANE, during ACCUTANE treatment, and for one month after stopping ACCUTANE. My physician has recommended that I either abstain from sex or use two reliable kinds of birth control at the same time even if I think I cannot become pregnant.
- Birth control methods may fail. No birth control method is absolutely safe. My physician has explained this to me. I must stop taking ACCUTANE and immediately contact my physician if:
  - My menstrual period is delayed during treatment.
  - I become pregnant while taking ACCUTANE or during the month after stopping ACCUTANE.
- I must discuss with my physician the desirability of continuing pregnancy, if I become pregnant.

I acknowledge that all the above points have been fully explained to me by my physician and that I clearly understand these points and the information on ACCUTANE provided to me.

Patient, Parent or Guardian Signature _____

Address _____ Telephone # _____

Physician Name _____ Date _____

For full prescribing information, please consult the ACCUTANE™ ROCHE® Product Monograph.

If you require this information in an accessible format, please contact Roche at 1-800-561-1759.

Appendix 4: Pregnancy Prevention Checklist

Title: Isotretinoin Therapy (Pharmacist)
Number: C-FHT07

Note to physician: Please retain a copy in the patient's file

Name of patient: Date:

Name of physician:

Pregnancy Prevention Checklist

ACCUTANE™ ROCHE® (isotretinoin) must not be used by females who are pregnant or who may become pregnant while undergoing treatment.

ACCUTANE is a severe teratogenic agent that is associated with major human fetal abnormalities. This checklist is supplied by Hoffmann-La Roche Limited to assist physicians in determining patient suitability when treatment with ACCUTANE is being considered for the female patient. It is recommended that this checklist be retained in the patient's file for convenient reference.

ACCUTANE is contraindicated in women of childbearing potential unless, after deciding the patient is an ACCUTANE candidate, you, the physician, are satisfied that they meet the criteria listed below. Please complete the following checklist:

If any NO box is checked, DO NOT prescribe ACCUTANE	YES	NO
1. The patient is reliable in understanding and carrying out all instructions.		
2. The patient is capable of complying with effective contraceptive measures (complete abstinence or simultaneous use of two effective forms of birth control) starting one month before, during, and one month after ACCUTANE therapy.		
3. The patient has received **oral and written warnings** of the hazards of taking ACCUTANE during pregnancy.		
4. The patient has been counselled on the risk of possible contraception failure and its consequences.		
5. The patient has had two negative pregnancy tests before starting ACCUTANE therapy with the first pregnancy test conducted at initial assessment when the patient is qualified for ACCUTANE therapy by the physician. The patient has had a second serum or urine pregnancy test with a sensitivity of at least 25 mIU/mL with a negative result, performed in a licensed laboratory, within 11 days prior to initiating therapy. The patient has had two or three days of the next normal menstrual period before ACCUTANE therapy is initiated.		
6. The patient is not a nursing mother.		
7. The patient understands the need for rigorous follow-up on a monthly basis and will schedule monthly appointments with you for monitoring.		
8. If the patient becomes pregnant, she understands that she must stop taking ACCUTANE immediately and call for an urgent appointment to discuss options concerning continuing the pregnancy.		
9. The patient will sign the consent to treatment form.		

If the answer to any of these questions is NO, then the patient must not receive ACCUTANE.

Because of the extremely high risk of birth defects, the patient should only be placed on ACCUTANE once you are satisfied that she has met the above criteria. Therapy should only begin on the second or third day of the patient's next normal menstrual period after confirmation of a negative pregnancy test taken in the preceding two weeks.

Avoid Pregnancy **Birth Control Counselling Hotline** **1-877-333-2263**

For full prescribing information, please consult the ACCUTANE™ ROCHE® Product Monograph.

If you require this information in an accessible format, please contact Roche at 1-800-561-1759

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Appendix 5: Psychiatric Assessment Checklist

Title: Isotretinoin Therapy (Pharmacist)
Number: C-FHT07

NOTE TO PHYSICIAN: PLEASE RETAIN A COPY IN THE PATIENT'S FILE
This material was developed by Roche, as part of the risk minimization plan for ACCUTANE™ ROCHE® (isotretinoin). This material is not intended for promotional use.

Name of Patient: _____ Date: _____

Name of Physician: _____

PSYCHIATRIC ASSESSMENT CHECKLIST

Some patients treated with ACCUTANE have become depressed and some attempted or committed suicide. Although a causal relationship has not been established, it is prudent to screen and monitor all patients for signs of depression prior to start of treatment and periodically during therapy.

The following information is contained in the Product Monograph for ACCUTANE:

Serious Warnings and Precautions

Psychiatric: Some patients treated with ACCUTANE have become depressed and some attempted or committed suicide. Although a causal relationship has not been established, all patients should be screened and monitored for signs of depression before and during therapy (see WARNINGS AND PRECAUTIONS, Monitoring and Laboratory Tests). Physicians should determine whether the patient may be depressed or has a history of depression including a family history of major depression before starting therapy with ACCUTANE. If symptoms of depression develop or worsen during treatment with ACCUTANE, the drug should be discontinued promptly and the patient referred for appropriate psychiatric treatment as necessary. However, discontinuation of ACCUTANE may not alleviate symptoms and therefore further psychiatric or psychological evaluation may be necessary.

Adverse Reactions

"Psychiatric Disorders: Depression, psychotic symptoms and, rarely, suicide attempts, suicide, and aggressive and/or violent behaviours (see WARNINGS AND PRECAUTIONS: Psychiatric). Depression has been reported during and after therapy. In some of these patients, depression has subsided with discontinuation of therapy and recurred when ACCUTANE therapy was reintroduced. Emotional instability has been reported with ACCUTANE."

For complete information please consult the Product Monograph at www.rochecanada.com/PMs/Accutane/Accutane_PM_E.pdf. The Consumer Information can be downloaded from http://rochecanada.com/PMs/Accutane/Accutane_PM_CIE.pdf for distribution to patient at the point of care. The Product Monograph and Consumer Information are also available by contacting the Roche Drug Information line at 1-888-762-4388.

All patients must sign the informed consent form prior to initiating therapy. This form is available via the www.acneandu.ca website or by contacting the Roche Drug Information line at 1-888-762-4388.

It may be useful for physicians to screen patients prior to prescribing ACCUTANE and/or monitoring patients whilst on their ACCUTANE therapy using available tools. Example included in this package is the Patient Health Questionnaire-9 (PHQ-9). Other checklists may also be available and appropriate in the physician's professional judgment.

Specific management of depression detected through screening is at the discretion of the physician.

The PHQ-9 (supplied with this checklist) is a self-assessment questionnaire to be completed by the patient for review by the physician. *Please be advised that this questionnaire has not been validated for use in patients taking isotretinoin products for treatment of acne.*

The patient input from PHQ-9 below is meant to provide guidance in assessing your patient's mental health status. This information, along with other clinical information, may be used to modify treatment or make further referrals to a psychiatric consult, upon clinical discretion on a case-by-case basis. A careful assessment of the patient's mental state should be made, including whether or not they have a personal or family history of psychiatric illness.

Patient Health Questionnaire-9 (PHQ-9)* Nine-Symptom Checklist

Name: _____ Date: _____

Over the *last 2 weeks*, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

(For office coding: Total Score _____ = _____ + _____ + _____)

If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

❒ **Not difficult at all** ❒ **Somewhat difficult** ❒ **Very difficult** ❒ **Extremely difficult**

Patient Health Questionnaire-9 (PHQ-9)* Scores

Name: _____ Date: _____

- It may be useful for physicians to screen patients prior to prescribing ACCUTANE and/or monitoring patients whilst on their ACCUTANE therapy using available tools. Example included in this package is the Patient Health Questionnaire-9 (PHQ-9). Other checklists may also be available and appropriate in the physician's professional judgment.
- Specific management of depression detected through screening is at the discretion of the physician.

PHQ-9 Score	Depression Severity
1 – 4	None
5 – 9	Mild
10 – 14	Moderate
15 – 19	Moderately Severe
20 – 27	Severe

*Reference: Kroenke K, Spitzer RL. The PHQ-9: a new depression diagnostic and severity measure. Psychiatric Annals 2002;32:509-521.

If you require this information in an accessible format, please contact Roche at 1-800-561-1759.