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# TERMS AND ELIGIBILITY CRITERIA – FREE NITYR® PROGRAM\_(THE “FREE NITYR® PROGRAM ELIGIBILITY CRITERIA”)

## 1 About this Free Program Eligibility Criteria

- 1.1 This Free Program Eligibility Criteria set out how, and on what basis, you may qualify as a Free NITYR® Program Eligible Patient (as defined below) in order to participate in a thirty (30) day NITYR® (nitisinone) Tablets free program (such thirty (30) day free NITYR® Program being the “**Free Program**”).
- 1.2 You should read this Free Program Eligibility Criteria carefully. References to “**we**”, “**us**” and “**our**” mean Cycle Pharmaceuticals Ltd.
- 1.3 By accessing or using our website to read this Free Program Eligibility Criteria or otherwise indicating your consent, you agree to be bound by the US [terms and conditions](#) of our website and also agree to comply with our [acceptable use policy](#) and [privacy policy](#). If you do not agree with and accept all of the terms of each of the aforementioned, you should stop using our website immediately.

## 2 Eligibility criteria

- 2.1 You are only eligible to participate in the Free Program if you are a “**Free Program Eligible Patient**”. For the purposes of this Free Program Eligibility Criteria (and subject always to, in particular (but not limited to) clauses 2.3 and 4 of this Free Program Eligibility Criteria), a Free Program Eligible Patient is a person who satisfies, in our discretion, all of the following criteria:
  - 2.1.1 a person who has a valid prescription for NITYR® (nitisinone) Tablets issued by his or her physician or other health care professional;
  - 2.1.2 a person who:
    - (a) through their physician or other health care professional, has successfully enrolled in the Free Program by completing and submitting to the NITYR® patient support program (“**the PSP**”) (who provide non-commercial pharmacy services for us and on our behalf) an enrolment form and who the PSP otherwise confirm have satisfied all patient benefit investigations, checks and similar. A copy of the Free Program enrolment form can be found at [www.nityr.us/free-program](http://www.nityr.us/free-program);
    - (b) is not enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, DOD, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico; and
    - (c) a person who is resident in the United States of America. Also, please see paragraph 2.3 of this Free Program Eligibility Criteria. For the purpose of this clause a resident of the United States of America does not include residents of the United States of America inhabited territories: American Samoa, Guam, Puerto Rico, the U.S. Virgin Islands and the Northern Mariana Islands.
- 2.2 Notwithstanding the foregoing, and qualification as a Free Program Eligible Patient, eligibility to participate in the Free Program is subject to:
  - 2.2.1 eligibility verification by the PSP;
  - 2.2.2 having a fully completed personal health information (“**PHI**”) disclosure form, which can be completed online at [www.nityr.us/consent](http://www.nityr.us/consent);
  - 2.2.3 applicable law; and
  - 2.2.4 the remaining terms of this Free Program Eligibility Criteria.
- 2.3 Caregivers of Free Program Eligible Patients (a “**Caregiver**”) will be permitted to participate in the Free Program for and on behalf of such Free Program Eligible Patients (and this Free Program Eligibility Criteria will be construed accordingly). Also, please see paragraph 2.4 of this Free Program Eligibility Criteria.

- 2.4 This offer is restricted to residents of the United States of America. If you are not resident in the United States of America, you will not be eligible to participate in the Free Program or otherwise qualify as a Free Program Eligible Patient.
- 2.5 If you are a Free Program Eligible Patient under the age of eighteen (18) years of age a Caregiver must act for and on your behalf. If you are a Caregiver acting for and on behalf of a Free Program Eligible Patient, you must be eighteen (18) years of age or older.
- 2.6 If you are in any doubt about whether or not you constitute a Free Program Eligible Patient, please contact the PSP on: 1-800-847-8714 (Monday to Friday 9 am to 5 pm EST).

### **3 Terms applicable to the Free Program**

- 3.1 The Free Program is subject to applicable law and, in particular (but not limited to), the provisions of clause 4 of this Free Program Eligibility Criteria.
- 3.2 If you are a Free Program Eligible Patient and have been enrolled on a Free Program you will:
  - 3.2.1 be entitled to be sent and to receive from the PSP thirty (30) days' worth of free NITYR® (nitisinone) Tablets;
  - 3.2.2 be sent a patient initiation document for NITYR® (nitisinone) Tablets; and
  - 3.2.3 be contacted by the PSP regarding, amongst other things, the commencement, operation and conclusion of the Free Program.
- 3.3 Participation in the Free Program by a Free Program Eligible Patient is non-transferable and exclusive to each Free Program Eligible Patient. Participation in the Free Program is limited to one Free Program per Free Program Eligible Patient. For the avoidance of doubt, a Free Program Eligible Patient may only participate in the Free Program once.

### **4 Other terms**

- 4.1 We reserve the right to rescind, revoke, or amend the Free Program, this Free Program Eligibility Criteria or any other terms applicable to the Free Program at our sole discretion and at any time without notice. Following any such rescission, revocation or amendment, you agree to be bound by the same. It is your responsibility to check this Free Program Eligibility Criteria from time to time.
- 4.2 No person (including for clarity any Free Program Eligible Patients, Caregivers and any prescribers of Free Program Eligible Patients) may seek reimbursement from any health insurance (including commercial insurance and/or any Federal or State Insurance Program). No claim for reimbursement for product dispensed pursuant to this offer may be submitted to any third-party payer, whether a private or government payer for all or any part of any NITYR® (nitisinone) Tablets supplied pursuant to the Free Program.
- 4.3 If you have any questions regarding the Free Program, please contact the PSP on: 1-800-847-8714 (Monday to Friday from 9 am to 5 pm EST).

### **5 Intellectual property rights**

- 5.1 **The term "intellectual property rights"** means rights such as: copyright, trademarks, domain names, design rights, database rights, patents and all other intellectual property rights of any kind whether or not they are registered or unregistered (anywhere in the world). We retain and reserve all of our respective rights in any intellectual property in connection with NITYR® (nitisinone) Tablets, the Free Program and this Free Program Eligibility Criteria.
- 5.2 You agree not to adjust to try to circumvent or delete any provisions of this Free Program Eligibility Criteria.
- 5.3 The trademarks: "NITYR®" and "Cycle®" are our trademarks. Other trademarks and trade names may also be used on our website and in this Free Program Eligibility Criteria. The use of any of our trade marks is strictly prohibited unless you have our prior written permission and the use of any of third-party trademarks is strictly prohibited unless you have the written permission of the relevant third party.

## **6 Accuracy of information**

None of the information set out in this Free Program Eligibility Criteria constitutes technical, financial, medical or legal advice or any other type of advice and should not be relied on for any purpose(s).

## **7 Limitation on our liability**

Except for any legal responsibility that we cannot exclude in law, we are not legally responsible, or otherwise liable, for any direct, indirect, incidental, consequential or special damages or injuries resulting from the reliance on this Free Program Eligibility Criteria or the Free Program.

For full prescribing information please visit: [www.nityr.us/PI](http://www.nityr.us/PI)

# TERMS AND ELIGIBILITY CRITERIA – PATIENT NUTRITION PROGRAM (THE “PATIENT NUTRITION PROGRAM ELIGIBILITY CRITERIA”)

## 8 About this Patient Nutrition Program Eligibility Criteria

- 8.1 This Patient Nutrition Program Eligibility Criteria set outs how, and on what basis, you may qualify as a Patient Nutrition Program Eligible Patient (as defined below) in order to participate in a free patient nutrition program (such Patient Nutrition Program being the “**Patient Nutrition Program**”).
- 8.2 You should read this Patient Nutrition Program Eligibility Criteria carefully. References to “**we**”, “**us**” and “**our**” mean Cycle Pharmaceuticals Ltd.
- 8.3 By accessing or using our website to read this Patient Nutrition Program Eligibility Criteria or otherwise indicating your consent, you agree to be bound by the US [terms and conditions](#) of our website and also agree to comply with our [acceptable use policy](#) and [privacy policy](#). If you do not agree with and accept all of the terms of each of the aforementioned, you should stop using our website immediately.

## 9 Eligibility criteria

- 9.1 You are only eligible to participate in the Patient Nutrition Program if you are a “**Patient Nutrition Program Eligible Patient**”. For the purposes of this Patient Nutrition Program, Eligibility Criteria (and subject always to, in particular (but not limited to) clauses 2.3 and 4 of this Patient Nutrition Program Eligibility Criteria), a Patient Nutrition Program Eligible Patient is a person who satisfies, in our discretion, all of the following criteria:
- 9.1.1 (i) a person who has a valid prescription for NITYR<sup>®</sup> (nitisinone) Tablets issued by his or her physician or other relevant and appropriately qualified health care professional; or (ii) a person who is wholly insured by commercial insurance and is currently enrolled on the thirty (30) day NITYR<sup>®</sup> (nitisinone) tablets program known as the Free Program and governed by the Free NITYR<sup>®</sup> Program Eligibility Criteria available at [www.nityr.us/offerstcs](http://www.nityr.us/offerstcs); and
- 9.1.2 a person who: is a resident in the United States of America. Also, please see paragraph 2.3 of this Patient Nutrition Program Eligibility Criteria. For the purposes of this clause a resident of the United States of America does not include residents of the United States of America inhabited territories: American Samoa, Guam, Puerto Rico, the U.S. Virgin Islands and the Northern Mariana Islands.
- 9.2 Notwithstanding the foregoing, and qualification as a Patient Nutrition Program Eligible Patient, eligibility to participate in the Patient Nutrition Program is subject to:
- 9.2.1 having a fully completed personal health information (“**PHI**”) disclosure consent form, which can be completed online at [www.nityr.us/consent](http://www.nityr.us/consent);
- 9.2.2 applicable law; and
- 9.2.3 the remaining terms of this Patient Nutrition Program Eligibility Criteria.
- 9.3 Caregivers of Patient Nutrition Program Eligible Patients (a “**Caregiver**”) will be permitted to participate in the Patient Nutrition Program for and on behalf of such Patient Nutrition Program Eligible Patients (and this Patient Nutrition Program Eligibility Criteria will be construed accordingly). Also, please see paragraph 2.4 of this Patient Nutrition Program Eligibility Criteria.
- 9.4 This offer is restricted to residents of the United States of America. If you are not resident in the United States of America, you will not be eligible to participate in the Patient Nutrition Program or otherwise qualify as a Patient Nutrition Program Eligible Patient.
- 9.5 If you are a Patient Nutrition Program Eligible Patient under the age of eighteen (18) years of age a Caregiver must act for and on your behalf. If you are a Caregiver acting for and on behalf of a Patient Nutrition Program Eligible Patient, you must be eighteen (18) years of age or older.
- 9.6 If you are in any doubt about whether or not you constitute a Patient Nutrition Program Eligible Patient, please contact patient liaison services on: 1-800-775-5783 (Monday to Fridays 9 am to 5 pm EST).

## **10 Terms applicable to the Patient Nutrition Program**

- 10.1 The Patient Nutrition Program is subject to applicable law and, in particular (but not limited to), the provisions of clause 4 of this Patient Nutrition Program Eligibility Criteria.
- 10.2 If you are a Patient Nutrition Program Eligible Patient and you have been enrolled on a Patient Nutrition Program you will:
- 10.2.1 receive initially weekly, followed by monthly, 30-minute calls on discussion topics designed and established by your clinic's health care professional and agreed with your clinic's dietitian in advance, to support your prescribed diet protocol and meet your goals, and
  - 10.2.2 be contacted by patient liaison services regarding, amongst other things, the commencement, operation and conclusion of the Patient Nutrition Program.
  - 10.2.3 **Discussion topics could include:**
    - (a) Support on following your clinic's prescribed dietary plan
    - (b) Support on understanding nutrition food labels
    - (c) Information about introducing solid foods
    - (d) Low protein recipe ideas, and
    - (e) Low protein grocery lists
- 10.3 Participation in the Patient Nutrition Program by a Patient Nutrition Program Eligible Patient is non-transferable and is exclusive to each Patient Nutrition Program Eligible Patient. Participation in the Patient Nutrition Program is limited to one (1) Patient Nutrition Program per Patient Nutrition Program Eligible Patient.

## **11 Other terms**

- 11.1 We reserve the right to rescind, revoke, or amend the Patient Nutrition Program, the Patient Nutrition Program Eligibility Criteria or any other terms applicable to the Patient Nutrition Program at our sole discretion and at any time without notice. Following any such rescission, revocation or amendment, you agree to be bound by the same. It is your responsibility to check this Patient Nutrition Program Eligibility Criteria from time to time.
- 11.2 No person (including for clarity any Patient Nutrition Program Eligible Patients, Caregivers and any prescribers of Patient Nutrition Program Eligible Patients) may seek reimbursement from any health insurance (including commercial insurance and/or any Federal or State Insurance Program). No claim for reimbursement for product dispensed pursuant to this offer may be submitted to any third-party payer, whether a private or a government payer for all or any part of any NITYR® (nitisinone) Tablets supplied pursuant to the Patient Nutrition Program.
- 11.3 If you have any questions regarding the Patient Nutrition Program, please contact patient liaison services on: 1-800-775-5783 (Monday to Friday from 9 am to 5 pm EST).

## **12 Intellectual property rights**

- 12.1 **The term "intellectual property rights"** means rights such as: copyright, trademarks, domain names, design rights, database rights, patents and all other intellectual property rights of any kind whether or not they are registered or unregistered (anywhere in the world). We retain and reserve all our respective rights in any intellectual property in connection with NITYR® (nitisinone) Tablets, the Patient Nutrition Program and this Patient Nutrition Program Eligibility Criteria.
- 12.2 You agree not to adjust or to try to circumvent or delete any provisions contained within this Patient Nutrition Program Eligibility Criteria.
- 12.3 The trademarks: "NITYR®" and "Cycle®" are our trademarks. Other trademarks and trade names may also be used on our website and in this Patient Nutrition Program Eligibility Criteria. The use of any of our trademarks is strictly prohibited unless you have our prior written permission and the use of any third-party trademarks is strictly prohibited unless you have obtained the written permission of the relevant third party.

**13 Accuracy of information**

None of the information set out in this Patient Nutrition Program Eligibility Criteria constitutes technical, financial, medical or legal advice or any other type of advice and therefore, it should not be relied on for this purpose(s).

**14 Limitation on our liability**

Except for any legal responsibility that we cannot exclude in law, we are not legally responsible, or otherwise liable, for any direct, indirect, incidental, consequential or special damages or injuries resulting from the reliance on this Patient Nutrition Program Eligibility Criteria or the Patient Nutrition Program.

For full prescribing information please visit: [www.nityr.us/PI](http://www.nityr.us/PI)

# TERMS AND ELIBILITY CRITERIA – Tyrosinemia Type 1 (“HT-1”) 1:1 Dietitian Support (“NITYR® DIETITIAN SUPPORT ELIGIBILITY CRITERIA”)

## 1 About this Dietitian Product Support

- 1.1 This Dietitian Product Support Eligibility Criteria sets out, subject to its remaining terms, how, registered dietitians and/or qualified nutritionists (“RD”) can receive one-on-one support through telephone or video calls to enhance their understanding of HT-1 nutritional management from birth to adulthood (the “Calls”). The Calls will provide an RD specialist in HT-1 from Cycle Pharmaceuticals Ltd who will be available to respond to specific HT-1 dietary questions (the “**Dietitian Product Support**”) relevant to the treatment of HT-1 patients who have been prescribed NITYR by an authorized Health Care Provider (HCP). The Dietitian Product Support is non-promotional, complimentary support offered solely for the purpose of enhancing the understanding of HT-1 nutritional management for eligible RDs in support of better HT-1 care.
- 1.2 You should read these Dietitian Product Support Eligibility Criteria carefully. References to “we”, “us” and “our” mean Cycle Pharmaceuticals Ltd.
- 1.3 By accessing or using our website to read these Dietitian Product Support terms and conditions or otherwise indicating your consent, you agree to be bound by the [terms and conditions](#) of our website and also agree to comply with our [acceptable use policy](#) and [privacy policy](#). If you do not agree with, or accept all of the terms of the aforementioned, you should stop using our website immediately.

## 2 Eligibility criteria

- 2.1 You are only eligible to participate in the Dietitian Product Support if you are an “**Eligible Dietitian**”. For the purposes of this Dietitian Product Support Eligibility Criteria (and subject always to, in particular (but not limited to) clause 2.3, 3 and 4 below), an Eligible Dietitian is a person who fulfils all of the following criteria:
  - (a) a person who is an RD who does not have practical experience of HT-1 nutritional management for the relevant Age Category (defined below).
  - (b) a person who is a resident in the United States of America. Also, please see paragraph 2.3 of this Free Program Eligibility Criteria. For the purpose of this clause a resident of the United States of America does not include residents of the United States of America inhabited territories: American Samoa, Guam, Puerto Rico, the U.S. Virgin Islands and the Northern Mariana Islands.

Age Category is defined as: (i) newborn to infants (zero to five years old inclusive); (ii) elementary school children (six to 12 years old inclusive); (iii) teenagers (thirteen to eighteen inclusive); and (iv) adults (19 years old and over).

- 2.2 Notwithstanding the foregoing, and qualification as an Eligible Dietitian, eligibility to participate in the Dietitian Product Support is subject to:
  - 2.2.1 appropriate verification;
  - 2.2.2 applicable law; and
  - 2.2.3 the remaining terms of this Dietitian Product Support Eligibility Criteria.
- 2.3 This Dietitian Product Support is restricted to residents of the United States of America. If you are not a resident in the United States of America, you will not be eligible to participate in the Dietitian Product Support. This offer is subject to applicable federal and state law.
- 2.4 The Dietitian Product Support is subject to applicable federal and state law. Accordingly, and subject to the remaining terms of this Dietitian Product Support Eligibility Criteria, not all Eligible Dietitians will be able to qualify for the Dietitian Product Support.

## 3 Terms applicable to the Dietitian Product Support.

- 3.1 The Dietitian Product Support is subject to applicable law and, in particular (but not limited to) the provisions of clause 4 of this Dietitian Product Support Eligibility Criteria.

- 3.2 The Dietitian Product Support will not and is not intended to offer any medical advice and should not be relied upon as such per Sections 6 and 7 herein.
- 3.3 The Dietitian Product Support is limited to calls totaling up to three (3) hours in aggregate to respond to HT-1 dietary questions. The date, time and duration of these calls will be scheduled with you at a later date. Examples of relevant HT-1 dietary questions for the calls may include, but are not limited to:
- How to create letters to inform a school about the nutritional needs of a child with HT-1;
  - What are the total caloric and protein requirements (all Age Categories);
  - How to design a metabolic formula plan and feeding schedule (newborns);
  - How to introduce solids and corresponding formula adjustments (newborns and infants); and
  - How to plan the distribution of natural protein allowance through the day (all Age Categories).
- 3.4 When the Eligible Dietitian has been successfully verified, they will receive information regarding the Dietitian Product Support and access thereto.

#### **4 Other terms**

- 4.1 We reserve the right to rescind, revoke, or amend this Dietitian Product Support, the Dietitian Product Support Eligibility Criteria, or any other terms applicable to it at our sole discretion and at any time without notice. Following any such rescission, revocation, or amendment, you agree to be bound by the same. It is your responsibility to check this Dietitian Product Support terms & conditions from time to time.
- 4.2 If you have any questions regarding the Dietitian Product Support terms and conditions, please contact [community@cyclepharma.com](mailto:community@cyclepharma.com).

#### **5 Intellectual property rights**

- 5.1 **The term “intellectual property rights”** means rights such as: copyright, trademarks, domain names, design rights, database rights, patents, and all other intellectual property rights of any kind whether or not they are registered or unregistered (anywhere in the world).
- 5.2 You agree not to adjust, try to circumvent, or delete any provisions of this Dietitian Product Support Eligibility Criteria.
- 5.3 The trademarks: “NITYR®” and “Cycle®” are our trademarks. Other trademarks and trade names may also be used on our website and in these Dietitian Product Support terms and conditions. The use of any of our trademarks is strictly prohibited unless you have our prior written permission and the use of any of third-party trademarks is strictly prohibited unless you have obtained the written permission of the relevant third party.

#### **6 Accuracy of information**

None of the information set out in this Dietitian Product Support Eligibility Criteria constitutes technical, financial, medical, or legal advice or any other type of advice and should not be relied on for any purpose(s).

#### **7 Limitation on our liability**

Except for any legal responsibility that we cannot exclude in law, we are not legally responsible, or otherwise liable, for any direct, indirect, incidental, consequential or special damages or injuries resulting from the reliance on this Dietitian Product Support Eligibility Criteria or the Dietitian Product Support.

For full prescribing information please visit: [www.nityr.us/PI](http://www.nityr.us/PI)

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