

**HCC LIFE INSURANCE COMPANY**  
**STOP LOSS POLICY**  
**QUALIFIED CLINICAL TRIALS ENDORSEMENT**

Policy Number:

Endorsement Number:

Policyholder:

Effective:

YOU and WE agree that this Policy is amended as follows:

ARTICLE I. DEFINITIONS is hereby amended to add the following:

**PATIENT CARE SERVICES.** Health care items or services that are furnished to an individual enrolled in a Qualified Clinical Trial, which is consistent with the usual and customary standard of care for someone with the patient's diagnosis, is consistent with the study protocol for the clinical trial, and would be covered if the patient did not participate in the Qualified Clinical Trial.

Patient Care Services must be determined to be eligible under the Policyholder's Employee Benefit Plan.

Patient Care Services do not include any of the following:

1. An FDA approved drug or device shall be a Patient Care Service only to the extent that the drug or device is not paid for by the manufacturer, the distributor or the provider of the drug or device, or
2. Non-health care services that a patient may be required to receive as a result of being enrolled in the Qualified Clinical Trial, or
3. Costs associated with managing the research associated with the Qualified Clinical Trial, or
4. Costs that would not be covered for non-investigational treatments, or
5. Any item, service or cost that is reimbursed or otherwise furnished by the sponsor of the Qualified Clinical Trial, or
6. The costs of services, which are not provided as part of the Qualified Clinical Trial's stated protocol or other similarly, intended guidelines.

**QUALIFIED CLINICAL TRIAL.** A Qualified Clinical Trial is a clinical trial that meets all of the following conditions:

1. The clinical trial is intended to treat cancer or another life threatening condition in a patient who has been so diagnosed, and
2. The clinical trial has been peer reviewed and is approved by at least one of the following:
  - a. A federally funded or approved Trial; or
  - b. A clinical trial conducted under an FDA investigation new drug application; or
  - c. A drug trial that is exempt from the requirement of an FDA investigational new drug application.
3. The patient meets the patient selection criteria enunciated in the study protocol for participation in the clinical trial.

Article VI, EXCLUSIONS. Item C is amended to include the following:

If your Employee Benefit Plan is compliant with Section 10103(c) of the Affordable Care Act, Covered Expenses for Patient Care Services furnished in connection with participation in Qualified Clinical Trials, as defined herein, will not be considered Experimental or Investigative.

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**ADDITIONAL QUALIFIED CLINICAL TRIALS PROVISIONS**

WE may require a copy of the Qualified Clinical Trial's study protocol before determining if any benefits are payable under this Endorsement.

We shall rely on the Employee Benefit Plan in terms of the definition of Life Threatening. Should the Employee Benefit Plan fail to provide a definition of Life Threatening, We will define Life Threatening as a condition that is expected to cause death within 6 months. Such definition will be used solely for the purposes of this policy and adjudication of any claims under this Endorsement.

Stop Loss Policy benefits paid under this Endorsement will be included in the Specific Contract Period Reimbursement Maximum, if applicable.

Stop Loss Policy benefits paid under this Endorsement shall not create any legal presumption that HCC Life Insurance Company has recommended, directed, endorsed or required any Covered Person's participation in the Qualified Clinical Trial.

Stop Loss Policy benefits paid under this Endorsement shall be subject to all terms and conditions of the Policyholder's Employee Benefit Plan.

**THERE ARE NO POLICY CHANGES UNDER THIS ENDORSEMENT OTHER THAN STATED ABOVE.**

\_\_\_\_\_  
Full Legal Name of Applicant/Policyholder:

\_\_\_\_\_  
Signed At / Date Signed

\_\_\_\_\_  
Officer/Partner Signature (print name)

\_\_\_\_\_  
Witnessed (Licensed Agent) Signature

**FOR HCC LIFE INSURANCE COMPANY USE ONLY:**

**ACCEPTANCE**

Accepted on behalf of the Company, this \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_

By \_\_\_\_\_

Title: \_\_\_\_\_