

**AMERICAN NATIONAL LIFE INSURANCE COMPANY OF TEXAS
STOP LOSS POLICY
QUALIFIED CLINICAL TRIALS ENDORSEMENT**

POLICY NUMBER: {INSERT}

ENDORSEMENT NUMBER: {INSERT}

EMPLOYER: {INSERT}

EFFECTIVE DATE OF ENDORSEMENT: {INSERT}

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

Page 3, 1. COVERAGE PROVISION B. is amended to include the following:

The Stop Loss Policy will reimburse Covered Expenses, in excess of the Specific Deductible, for Patient Care Services furnished in connection with participation in Qualified Clinical Trials as defined by this Endorsement.

Qualified Clinical Trials – Definition

A Qualified Clinical Trial is defined as a clinical trial that meets all of the following conditions:

1. The clinical trial is intended to treat cancer 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. One of the United States National Institutes of Health,
 - B. A cooperative group or center of the National Institutes of Health,
 - C. A qualified nongovernmental research entity identified in guidelines issued by the National Institutes of Health for center support grants,
 - D. The United States Food and Drug Administration pursuant to an investigational new drug exemption,
 - E. The United States Departments of Defense or Veterans Affairs,
 - F. Or, with respect to Phase II, III and IV clinical trials only, a qualified institutional review board and,
3. The facility and personnel conducting the clinical trial are capable of doing so by virtue of their experience and training and treat a sufficient volume of patients to maintain that expertise, and
4. The patient meets the patient selection criteria enunciated in the study protocol of participation in the clinical trial, and
5. The patient has provided informed consent for participation in the clinical trial in a manner that is consistent with current legal and ethical standards and,
6. The available clinical or pre-clinical data provide a reasonable expectation that the patient's participation in the clinical trial will provide a medical benefit that is commensurate with the risks of participation in the clinical trial, and
7. The clinical trial does not unjustifiably duplicate existing studies, and
8. The clinical trial must have a therapeutic intent and must, to some extent, assess the effect of the intervention on the patient.

Patient Care Services – Definition

Patient Care Services are defined as 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 Employer's Employee Benefit Plan Document.

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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.

Additional Provisions

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

Stop Loss Policy benefits paid under this Endorsement will be included in the Specific Lifetime Reimbursement Maximum.

Stop Loss Policy benefits paid under this Endorsement shall not create any legal presumption that American National Life Insurance Company of Texas 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 Employer's Employee Benefit Plan Document.

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

American National Life Insurance Company of Texas



SECRETARY



PRESIDENT