

**STUDY INITIATION 201.2
INSURANCE PRE-AUTHORIZATION
INSURED AND NON-INSURED**

1. PURPOSE

This policy describes the insurance verification and pre-determination process for clinical trial patients within Nebraska Medicine.

2. SCOPE

This process pertains to the completion of insurance pre-authorization for all patients who are eligible to participate or who have consented to participate in a therapeutic clinical trial at UNMC and Nebraska Medicine.

3. DEFINITIONS

Pre-determination: This term is often used interchangeably with Pre-Authorization.

The pre-determination of benefits process allows the medical provider to send the insurance company a statement listing proposed treatments or tests. Within a specified time period (i.e. Days, possibly weeks), the insurance company will generally respond with a statement noting that the treatment or test is approved (authorized) or not. A pre-determination number is often provided.

Insurance verification: The Patient Access Services (PAS) Financial Counselor will contact the insurance company to review patient specific benefits and coverage.

Study synopsis: A brief description of the study purpose and treatment plan.

Study matrix: The study matrix is a table noting which study tests/procedures are considered standard of care and will be submitted to insurance and which study tests/procedures are considered study related and will be covered under the study.

Clinical Trial Exclusion Clause: This clause may be written into the patient's insurance policy. The patient is financially liable for all costs related to the clinical trial in this case.

SOC: Standard of Care as determined by the Coverage Analysis.

4. PROCEDURE

A. INSURANCE REVIEW –

ALL patients who are eligible to participate or who have consented to participate in a therapeutic clinical trial will be subject to primary and secondary insurance verification by PAS Financial Counselors.

Step 1. For the patient who has been identified as eligible for consent or a patient who has already consented, the Research Coordinator will submit the Clinical Trial Insurance Predetermination Form to Patient Access Services. The patient should be made aware that a request will be submitted for information from their insurance payer.

Information that should be included with the form: Study synopsis and Study Matrix

The form, including the attachments should be emailed to Patient Access Services (PASFinancialCounselor@nebraskamed.com):

- Subject line of email should read; Clinical Trial Patient Protocol Pre-Authorization Request
- IF YOUR PATIENT IS HIGH PRIORITY (i.e. inpatient Leukemia, urgent treatment needed) please communicate this in your subject line and in the body of the email.

Step 2. The Patient Financial Counselor will review the patient's insurance coverage.

- a. The patient's individual policy will be reviewed to determine whether it has a clinical trial exclusion clause.
- b. The PAS Financial Counselor will complete the second part of the Clinical Trial Insurance Predetermination Form and email it back to the Research Coordinator with the insurance information.
- c. The PAS Financial Counselor will inform the Research Coordinator whether or not it is okay to proceed with study treatment and if there are any other concerns related to insurance or personal financial obligations for the patient.
- d. If there is no exclusion clause the PAS Financial Counselor will proceed with a Pre-authorization if required by the insurance policy. It is not necessary to wait for receipt of the pre-authorization number to start treatment, unless advised to do so by the PAS Financial Counselor.
 - A cover letter from the Vice Chancellor for Research will be submitted with all requests for pre-authorization to insurance payers. The cover letter provides explanation of the clinical trial review and approval process at our institution.
 - A cost estimator will be used to provide the best estimate of the cost of services provided when participating in a clinical trial. Items designated on the matrix as being billed to insurance will be used in the cost estimation with the exception of medications from the pharmacy.
- e. If the policy has a clinical trial exclusion clause, the patient should be made aware by the Research Coordinator. The patient should know that he/she is financially liable for all costs related to the clinical trial in this case and what those costs include at this point by PAS. At this time, the patient has the option to request an appeal, which in this case may cause a delay in the start of treatment. Or the patient may opt to request pre-authorization and proceed with the treatment without waiting for the response from the insurance payer. The patient should be informed that he/she is

financially liable for all charges if pre-authorization for the clinical trial is denied. Or the patient may decide to not participate in the clinical trial.

- If the patient decides to assume financial responsibility a financial assessment will be completed with Patient Access Services. They will be provided with a cost estimate to inform them of their out-of-pocket costs, they will need to sign a non-cover waiver form and will be given a copy of the finance and patient collection policy.
 - Notify the IRB if a patient is denied coverage and chooses to continue participation in the trial.
- f. In the case of the un-insured, Patient Access Services will provide direction and instruction on health care coverage options for the patient. Access Financial Counseling may personally contact the patient to discuss these options and assist in the initiation of the required paperwork. Patient care should be delayed until Access Financial Counseling determines it is okay to proceed with the clinical trial. Until health care coverage is established for the patient, the patient should know that he/she is financial liable for all costs related to the clinical trial.

B. DOCUMENTATION

All correspondence between Research Coordinator and PAS Financial Counselor will be documented on the Clinical Trial Insurance Predetermination Form. All entries and/or changes to information on the form should be dated.

The Research Coordinator should print out the communication for the study file.

The Research Coordinator should document significant issues and communications with the patient in the patient electronic medical record. (i.e. patient request to move forward without pre-authorization – informing the patient that he/she is financially liable – and noting the patient understanding).

Patient Access Services will document all communication with the insurance payer as per their standard practice.

5. RESPONSIBILITY

The contents of this procedure apply to all clinical trials personnel and patient financial counselors.

6. REFERENCES

7. ATTACHMENTS

A-5 Clinical Trial Pre-Authorization Request form

A-6 Cover letter from Vice Chancellor for Clinical Research