# Investigational Device Submission to MAC or CMS Guidance Document

**Overview**

University of Texas Southwestern Medical Center is required to submit all Investigational Device Exemptions (IDE) Category A and B devices for approval to the Medicare Administrative Contractor (MAC) or Centers for Medicare & Medicaid Services (CMS) prior to clinical study initiation, if the study intends to bill Medicare or other third party payer. This is done in conjunction with Coverage Analysis review process. This guidance document details the submission process to the MAC and CMS.

**If an IDE was approved by the FDA prior to January 1, 2015**

For any approvals done prior to January 1, 2015, requests must be printed out and faxed to the Texas Medicare Administrative Contractor (MAC).

Documents that currently need to be included are:

1. Institutional Review Board (IRB) Approval Letter with expiration date.
2. Informed Patient Consent Form with patient signature page.
3. Protocol, which includes "Therapeutic Intent."
4. FDA Letter-Un-redacted, no white out or black outs, and must include the Signature Page. FDA Approval must be prior to January 1, 2015.
5. Submission Checklist.

UT Southwestern Clinical Research Services will act as a liaison between the MAC and the Investigator, including collection of the final approval letter from the MAC.

Upon receipt of the MAC letter, Clinical Research Services will upload a copy of the letter in Velos, "Documents" tab for study history documentation.

Clinical Trial Study Status in Velos will be updated to "Coverage Analysis-MAC Approval."

**If an IDE received FDA approval on or after January 1, 2015**

For any approvals done on or after January 1, 2015, requests must be submitted through the CMS website at https://www.cms.gov/Medicare/Coverage/IDE/index.html

Documents to be submitted include the following:

1. A request letter that describes the scope and nature of the IDE study. The letter should focus on how the IDE study meets each of the regulatory Medicare coverage IDE study criteria. A checklist and sample crosswalk is available to assist submitters.
2. FDA Approval Letter of the Category A or B IDE.
3. IDE study protocol.

4. Institutional Review Board (IRB) approval letter.
5. National Clinical Trial (NCT) number (e.g., NCD00000123).
6. Supporting materials, as appropriate.

Study team is responsible for facilitating approval request from CMS.

Study team is responsible for uploading CMS approval letter in the "Documents" tab in Velos for proper study history documentation.

CMS will post IDE study approvals on their website at:
https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html

Clinical Trial Study Status in Velos will be updated to "Coverage Analysis-MAC Approval" by the Central Coverage Analysis Group (CCAG) once they receive a copy of the CMS IDE approval letter.

References:

www.novitas-solutions.com

https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html

https://www.cms.gov/Medicare/Coverage/IDE/index.html