Device Studies at Stanford

Device Description	Medicare Preauthorization/ Noridian Notification Required?	Details
510K Device	NO	Routine Care costs billable to insurer
Post Market Approval (PMA) Device	NO	Routine Care costs billable to insurer
Non-Invasive diagnostic device or sampling method?	NO	Routine Care costs billable to insurer
Significant Risk (SR) Device – i.e. studies conducted under an IDE	**Yes***	Reasonable and necessary costs billable to insurer
Non-SR Device	NO	Routine Care costs billable to insurer

*PreAuth/Notification NOT required when documentation received that sponsor will cover **all** clinical care costs of study.

Device studies with CMS coverage under Medicare's NCD **Coverage with Evidence Development (CED)** do not require PreAuth/Site Notification to be sent to Noridian.

Device studies with IDE for a **Breakthrough Medical Devices (BMD)** device require PreAuth/Site Notification to be sent to Noridian.