

Managed Markets and Reimbursement

At TAMM Net, we start by performing an analysis of the reimbursement landscape for your product and its competition or related procedures. We provide you with candid recommendations and opinions on what is likely or not likely to be acceptable to payers, so that together we can develop an approach that has the greatest chance of success. Our relationships with payers, and the ability to relate to them in a manner that they understand, brings value to our clients. We conduct health economic analyses and produce publications to support the value of your product and quantify the size of the market. Claims data can be used to validate call points and sites of care.

TAMM Net prioritizes payers by commercial impact on your market segment to begin the process of gaining coverage. By working with your thought leaders, we obtain appropriate coding and coverage through societies and CMS. We communicate proper coding and product introductions to private insurers nationwide and work with individual plans to ensure coverage. Then, we work with payers to incorporate your product into their clinical treatment guidelines.

We are your call center performing prior authorizations and responding to questions from the field and headquarters. In the field, TAMM Net assists sales force training and develops reimbursement guides for reps and providers. This work includes content for internal and external websites and other materials.

Reimbursement tasks we routinely perform for our clients:

- Analysis, planning, and execution
- Integrate reimbursement into a pivotal trial
- Health Economic Outcomes Research (HEOR)
- Attain proper coding via AMA, CMS, and the BCBS Association
- Gain CMS coverage for Clinical Trials
- Budget impact Analysis/Value Proposition
- Communicate proper coding to insurers
- Get treatment into clinical pathways
- Payer assessment
- Health economic analysis
- Market preparation
- Conduct competitive analysis

Quality Systems and Regulatory Affairs

From pathway assessment and strategy to final clearance or approval, TAMM Net has the knowledge and relationships to expedite the regulatory process. Our professionals can guide you to develop your quality system or custom design and write it. Then, we will train your team on implementation and compliance.

We strategically consult and negotiate with the appropriate regulatory application with the FDA to obtain a successful outcome. We perform facility audits for both Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP), and conduct system and process validations. Whether you need to outsource your VP Regulatory Affairs, or just need a facility audit, TAMM Net has the expertise.

Regulatory tasks we routinely perform for our clients:

- Develop regulatory strategy
- Coordinate with research activities
- File regulatory documents
- Develop a publications strategy
- Perform compliance auditing: GMP, GLP
- Assist in preparing and submitting: IND, IDE, 505(b)(2), 510(k), PMA, ANDA, 513, BLA, and NDA
- Perform due diligence for competitive issues