

Regence

Medical Device/Technology Questionnaire

Please be prepared to answer all the items described below when meeting with Regence medical policy clinicians and medical directors.

- Description of the product
- Is it a new entity?
- Approval date/anticipated market date
- What is it used for?
- What are the alternatives to this product?
- What are the product's potential advantages that make it different from other alternatives?
- How does your company plan to market this product?
- How many representatives will be out in the field? Who will they be detailing?
- What are the market projections for this product?
- What are the results from clinical trials that directly relate to health outcomes? If the product is a diagnostic test, describe results specific to clinical utility.
- What types of patients were studied? How long were they studied/followed?
- What were the endpoints?
- What other studies are currently in progress or anticipated in the future?
- Describe the product's safety profile. Is it potentially better than other treatment/diagnostic options?
- Are there any other conditions where this product has shown promise?
- What is the cost of the product? If this is not available, what do you anticipate the product cost to be?
- Please provide any literature citations for published clinical trials specific to the product. If available, please provide hard copies of the relevant literature.