

# What Reimbursement Pathways Exist for a Novel Combination Product Regulated by CDER?

## *Reimbursement Pathway Assessment*



- Novel wound product combining a drug and device faces an uncharted market access path in the US because it will be one of the first wound products regulated by CDER
- The client required an understanding of coverage and reimbursement given this regulatory pathway, with the hope of being covered by Part D but needing to prepare for Part B

## *Health Advances Approach*



- Clarified the key drivers of payer decision-making, coverage and/or formulary determinations given the product profile and the likely regulatory pathway
- Illustrated Medicare coverage determination for drugs and devices
- Completed detailed case studies on the reimbursement pathway, evidence, and uptake of analog products

## *Outcome*



- Determined that it is likely that the product could be covered by Part D with proper trial design
- Educated the client on tactics to address Part D payers
- Acknowledged certain risks exist to Part D coverage and provided critical success factors as a Part B drug also