

Product Concept: Description of intervention

I. Executive summary

- Description of product concept and fit into existing treatment options for disease/condition
- Current health policy and trends including existing codes and reimbursement
- Clinical and economic summary of product concept compared to reasonable alternatives
- Statement of patient benefits and fit into healthcare marketplace

II. US Health Policy (Current and Trends)

III. US coverage policy environment

- a. Medicare
- b. Medicaid
- c. Private Payer

II. US Coding environment (ICD-10, CPT, PLA-CPT, HCPCS)

- a. Hospital Inpatient
- b. Hospital Outpatient
- c. Ambulatory Surgery Centers
- d. Post-acute care facilities
- e. Lab Services
- f. Physician Services

III. US reimbursement (payment) environment

- a. National Medicare base payment for reference purposes only

V. Global health economic environment

- a. Global Health Technology Assessments (HTA)
- b. Abbreviated clinical & economic literature search results
- c. Health economic value proposition:
 - Comparator/s
 - Patient Outcome Endpoints
 - Costs