QUESTIONS TO ASK WHEN DETERMINING REIMBURSEMENT STRATEGY

| Questions | Notes |
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| **Device/Product** |  |
| Explain how the device/product works |  |
| Is this a new product offering or it is an improved iteration of an existing device? If an iteration, how is it different from existing products? |  |
| Is the device inserted or implanted? Permanently or temporarily? |  |
| What type of provider(s) see these patients? |  |
| Is the procedure primarily diagnostic or therapeutic? |  |
| What is the estimated percentage of time that the procedure will be performed/used in each site of service: | * Inpatient hospital: * Outpatient hospital: * ASC: * Provider office or office-based lab: * Patient home: |
| What is the likely payer mix? | * Medicare: * Medicaid: * Work comp: * Commercial: * Other: |

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| **FDA** |  |
| What is the regulatory strategy? |  |
| What are the likely indications/patients for this technology? |  |
| Does or will the device have Breakthrough Device Designation? |  |
| When is FDA approval or clearance anticipated? |  |
| **Coding** |  |
| Are there any existing CPT codes that will apply (and has it been vetted by the relevant medical society)? |  |
| What ICD-10-PCS procedure codes will be used? |  |
| Will any HCPCS codes be used? |  |
| **Clinical Study and Publication Strategy** |  |
| Is a clinical trial planned or underway? What is the comparator, what are the relevant endpoints, and has it been vetted by any relevant payers? |  |
| If the device is still being studied, is it covered under an IDE Category A or B? |  |
| Are you charging hospitals for the device in the clinical trial? |  |
| What is the publication strategy? |  |
| **Sales and Marketing** |  |
| What is the estimated pricing (system, components)? |  |
| What is the launch plan (limited or entire US)? |  |
| What is the expected volume of use in the first year? |  |
| **Financing / Business Plan** |  |
| Are you positioning for acquisition or strategic investment? |  |

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| **DME Questions** | **Notes** |
| Product name |  |
| FDA pathway |  |
| Estimated FDA approval or clearance |  |
| Predicate device |  |
| Proposed indication |  |
| Disposables |  |
| Refurbishment program |  |
| Warranty |  |
| Average age of patient |  |
| Rent or own |  |
| Number of Medicare patients in trials |  |
| ASP of the product |  |
| Potential codes to consider |  |