

A presentation slide with a background of a stylized American flag. The text is centered and reads: "US Healthcare Reimbursement" in a large blue font, "Keys to successful product launch" in a smaller grey font, "Edward J. Dougherty" in a blue font, and "15-Apr-2026" in a grey font. A small blue "cl." logo is in the bottom left corner.

**US Healthcare Reimbursement**

Keys to successful product launch

Edward J. Dougherty  
15-Apr-2026

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A presentation slide with a white background. The text is left-aligned and reads: "Agenda" in a blue font, followed by a bulleted list: "Current state of play", "Health insurance in the US", "Reimbursement system(s)", "Payment for value", and "Implications for product launch". A small blue "cl." logo is in the bottom left corner, and a small "2" is in the bottom right corner.

**Agenda**

- Current state of play
- Health insurance in the US
- Reimbursement system(s)
- Payment for value
- Implications for product launch

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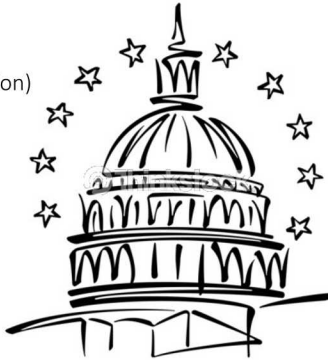
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## State of play

- Disruption, division, departures
- Narrow majorities - - disengagement
- Federal government - - chaos
- Current issues:
  - Global economy, 'affordability,' Iran
  - Petrol \$4.19/gallon in DC (~\$7.50/gallon in London)
  - 'TrumpRx,' price transparency
- Tariffs on drugs/devices?
- Future of public health/guidelines?
- Resolution . . . ?






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## Impact on your product launch

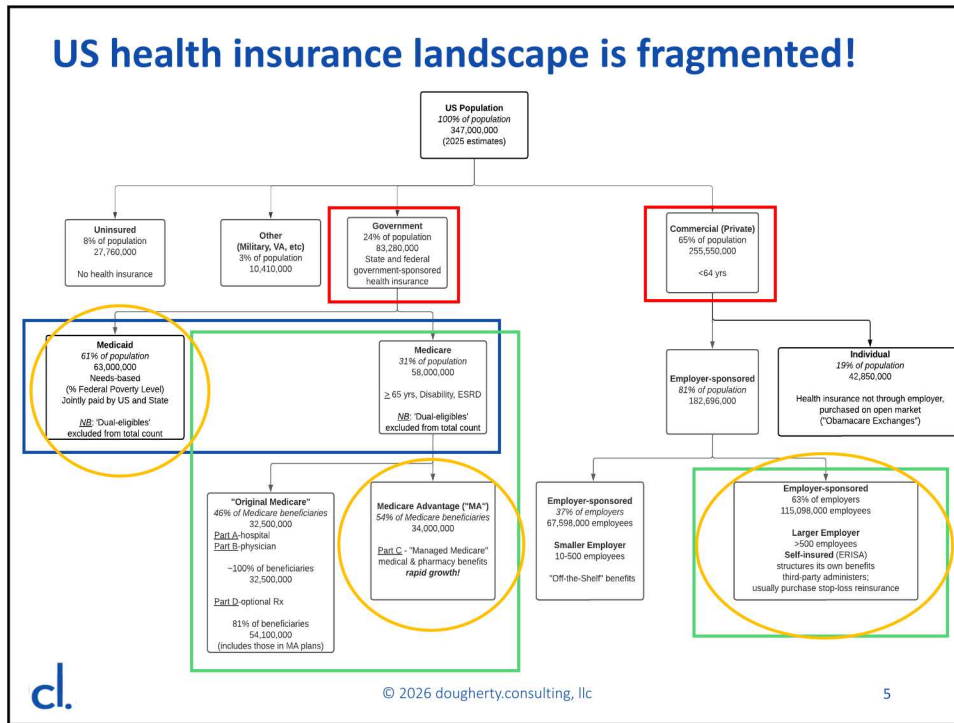
	Issue	Impact	Industry Response
Regulation <b>[FDA]</b>	<ul style="list-style-type: none"> <li>▪ Deregulation</li> <li>▪ Fed gov't RIFs</li> <li>▪ Lost expertise</li> <li>▪ Politics in gov't</li> </ul>	<ul style="list-style-type: none"> <li>▪ Accelerate or slow premarket review</li> <li>▪ New QMSR, standards, FDA guidances</li> </ul>	<ul style="list-style-type: none"> <li>▪ Engage reviewers early</li> <li>▪ Plan for longer timeline</li> </ul>
Reimbursement <b>[Payers]</b>	<ul style="list-style-type: none"> <li>▪ 'Efficiency adjustments'</li> <li>▪ Primary care</li> </ul>	<ul style="list-style-type: none"> <li>▪ Bundling</li> <li>▪ Provider pay cuts</li> </ul>	<ul style="list-style-type: none"> <li>▪ Address provider losses</li> <li>▪ Highlight impact on workflow, etc.</li> </ul>
Costs of healthcare & insurance <b>[Payer, provider]</b>	<ul style="list-style-type: none"> <li>▪ 'Obamacare' tax credits expired, premiums +100%</li> <li>▪ Employers' costs of benefits +9%</li> </ul>	<ul style="list-style-type: none"> <li>▪ Reduced benefits</li> <li>▪ Cost shifting to beneficiary</li> </ul>	<ul style="list-style-type: none"> <li>▪ Product features improve efficiency, reduce readmissions, enhance outcomes, lower cost</li> </ul>
Market adoption <b>[Provider, system]</b>	<ul style="list-style-type: none"> <li>▪ Tariffs</li> <li>▪ New tech assessments</li> </ul>	<ul style="list-style-type: none"> <li>▪ Expanded value analysis</li> <li>▪ Longer sell cycle</li> </ul>	<ul style="list-style-type: none"> <li>▪ Plan for longer cycle</li> <li>▪ Explore partnerships</li> <li>▪ Equip sales team with proper 'tools'</li> </ul>



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## Partner with payment innovators

**Self-insured employers**

- Fund employees' benefits
- Focus on balancing value/cost
- Flexible to add any product/benefit

**Medicare Advantage**

- Risk-adjusted lump sum payments
- Differentiate in competitive market
- Able to capture costs, treatment outcomes, 'value'

**Medicaid**

- Significant budget constraints
- Open to 'partner for value'

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## Just ask five questions . . .

Questions	Why is this important?
(a) What does your product do?	<input type="checkbox"/> Helps you articulate the product's intended use. ( <b>Unique value proposition</b> )
(b) Who is the target patient?	<input type="checkbox"/> Patient demographics help identify who the relevant <b>payers</b> are.
(c) Where will the service be provided?	<input type="checkbox"/> Site of service (e.g., hospital inpatient, surgical center, physician's office) helps identify which <b>payment systems</b> will apply, i.e., whether and how the product will be covered and reimbursed.
(d) How is the service being performed <b>now</b> (i.e., before your product comes to market)?	<input type="checkbox"/> Helps you understand the current flow of the <b>practice of medicine</b> in the US – does the product fit within the standard treatment pathway of these types of patients for this condition?
(e) Are there similar products on the US market now?	<input type="checkbox"/> Helps you evaluate ' <b>payment neighborhood</b> ' for your product/service, and if that amount is too low, allows you to develop a strategy to secure a payment amount more consistent with the product's demonstrated ' <b>value.</b> '



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## The answers indicate reimbursement pathway

Let's say you have a new implantable device for hearing loss . . .

Questions	Why is this important?
(a) What does your product do?	<input type="checkbox"/> Cochlear implant: ' <b>smart cochlear implant system</b> '
(b) Who is the target patient?	<input type="checkbox"/> Adults $\geq$ 18 yrs/age: <b>Payers:</b> Government & Commercial <b>Coverage:</b> Members with bilateral moderate to profound hearing loss
(c) Where will the service be provided?	<input type="checkbox"/> Site of service: Hospital outpatient, ambulatory surgery <b>Payment systems:</b> APC, ASC facility & surgeon payment.
(d) How is the service being performed <b>now</b> (i.e., before your product comes to market)?	<input type="checkbox"/> <b>Practice of medicine: same day procedure:</b> <u>CPT 69930</u> : \$1,176 (surgeon payment) <u>APC 5166</u> : \$31,807 (facility payment, device payment bundled) <u>ASC J8</u> (device intensive procedure): \$27,600 (facility & device)
(e) Are there similar products on the US market now?	<input type="checkbox"/> Helps you evaluate ' <b>payment neighborhood</b> ' <u>Device</u> : \$23,000 <u>Service</u> : \$6,500 <b>Value: standard implant v. 'smart' implant</b>



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### Your customers focus on 'payer mix'

Reimbursement

Coverage

Coding

Payment

Payer mix

- Policy set at population level regarding whether the product or service is **"reasonable and necessary"** based on peer-reviewed evidence
- If no formal policy exists, coverage based on clinician's determination of "medical necessity" for specific patient

- Diagnosis code: ICD-10-CM
- Outpatient procedure codes: APCs [facility]
- Physician/surgeon professional service code: CPT
- Product codes: HCPCS

- If diagnosis and procedure "match," i.e., specific procedure covered for treating diagnosis, it can be reimbursed
- Two payments are made:
  - Facility paid for cost of device and procedure
  - Surgeon paid for professional services

- 'Original Medicare:' ~94% cost
- Medicare Advantage (MA): ~105% Original Medicare
- Medicaid: ~85% cost
- Commercial: ~130-140% Medicare

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### Payer mix drives provider revenue

COPD Population by Payer — UCLA Estimate

Payer Type	Percentage
Original Medicare (FFS)	31%
Medicare Advantage	25%
Commercial / Employer	22%
Medi-Cal (Medicaid)	13%
Dually Eligible	4%
Other / Uninsured	5%

Source: UCLA 2025 Chargemaster

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## So, where do you stand?

- ✓ AI/ML
- ✓ SaMD/SaaS
- ✓ LDTs
- ✓ RPM/telehealth
- ✓ Others

### Hurdles


- Payment for device bundled with payment for procedure
- Current reimbursed amount won't cover cost of device


### Opportunities

- Professional and facility coding is already in place
- Potential transitional pass-through payment

### Next steps

- Plan to apply for pass-through payment bump
- Ensure evidence meets requirements



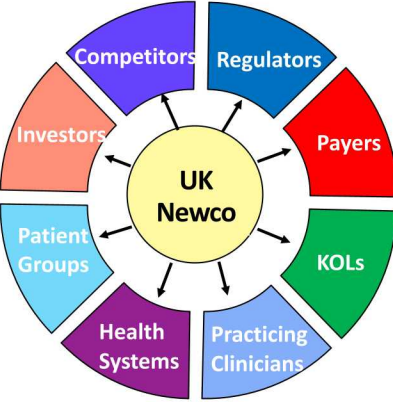


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## Evidence 'cascade' to target stakeholders



Stakeholders	Interest
Regulators	'Safe & effective'
Payers	'Reasonable, necessary, appropriate; cost-effective'
KOLs	'Improve SOC'
Practicing clinicians	'Optimize practice flow'
Patients	'Outcomes, QoL'
Patient groups	'Defeat cancer'
Investors	ROI
Competitors	Intelligence ....



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## Strategic evidence cascade

Study	Evidence cascade	Evidence	Audience
1	<ul style="list-style-type: none"> <li>Safety of device in healthy population</li> <li>Effectiveness in target population</li> </ul>	<ul style="list-style-type: none"> <li>Safe &amp; effective</li> </ul>	FDA
2	<ul style="list-style-type: none"> <li>'Real world' patients in routine practice</li> <li>Data linked to registries</li> </ul>	<ul style="list-style-type: none"> <li>Population data</li> <li>Reflect US demographics</li> </ul>	Payers, patients
3	<ul style="list-style-type: none"> <li>Safety &amp; performance in high-risk population</li> </ul>	<ul style="list-style-type: none"> <li>Performance data in target group</li> </ul>	KOLs
4	<ul style="list-style-type: none"> <li>Implementation in clinical practice flow</li> <li>'Practice optimization'</li> </ul>	<ul style="list-style-type: none"> <li>Fits within clinical flow</li> </ul>	Practicing clinicians
5	<ul style="list-style-type: none"> <li>'Real world' patients in health systems &amp; integrated delivery networks (IDNs)</li> </ul>	<ul style="list-style-type: none"> <li>Outcomes &amp; down stream impact</li> </ul>	Health systems
6	<ul style="list-style-type: none"> <li>Clinical utility when added to Standard of Care (SoC)</li> </ul>	<ul style="list-style-type: none"> <li>Treatment guidelines</li> </ul>	KOLs, payers
7	<ul style="list-style-type: none"> <li>Single arm prospective multicenter</li> </ul>	<ul style="list-style-type: none"> <li>Device optimization</li> <li>NexGen development</li> </ul>	Company
8	<ul style="list-style-type: none"> <li>Target group: Multicenter prospective cohort</li> <li>Control group: Passively-enrolled matched</li> <li>Long-term follow up</li> </ul>	<ul style="list-style-type: none"> <li>Clin/cost effective</li> <li>'Value'</li> </ul>	Multiple publications; all audiences

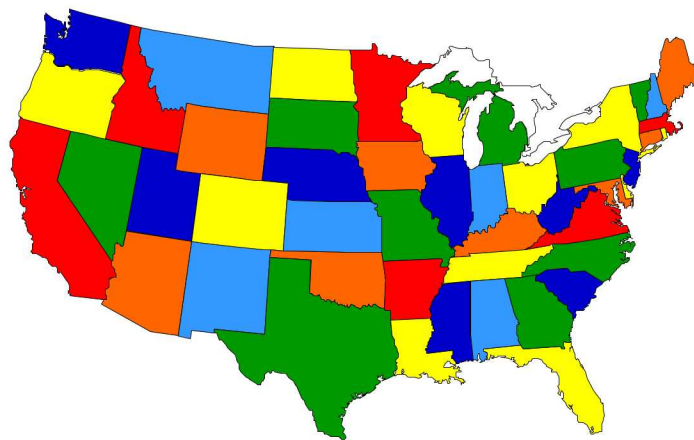


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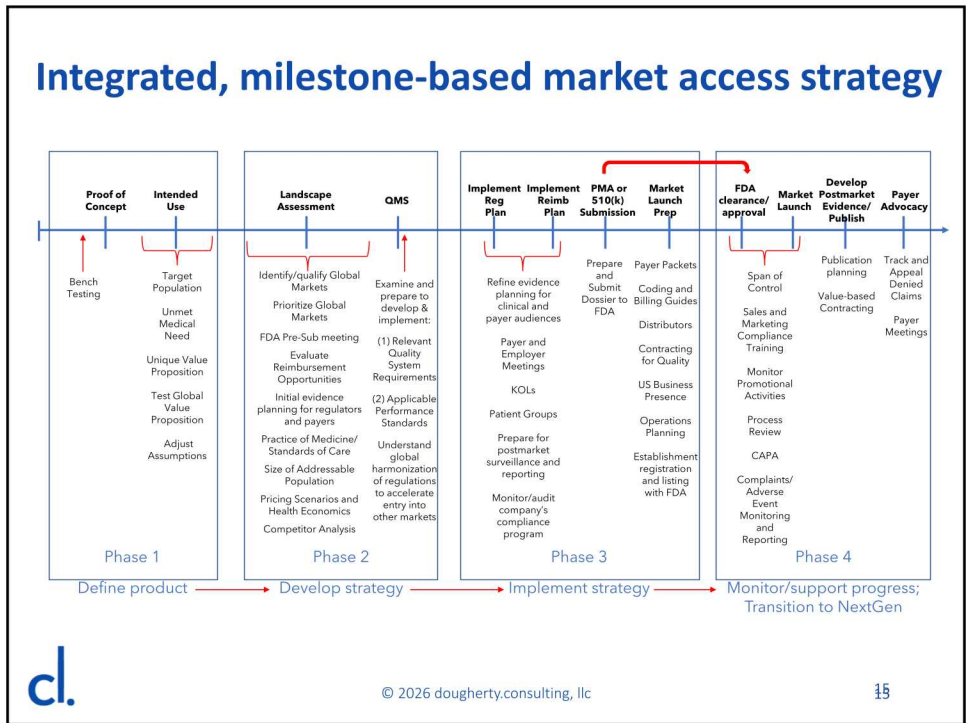
## Where should we start?



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### If they like it, they'll figure out how to pay for it. . .

- ❑ Get to know the landscape
  - ❑ Practice flow, contracting, costs to provide/pay for care
- ❑ Develop an initial strategy, adjust as needed
  - ❑ Investor overview
  - ❑ Priority setting for strategic direction
- ❑ Focus on the 'big picture,' not the details
  - ❑ Don't start with 'billing codes!!'
- ❑ Budget for the resources you need
  - ❑ Data, analysts, consultants
  - ❑ Pilot programs with payers
- ❑ Get started now

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