WEBINAR

MedTech at Home:

Key Regulatory and Reimbursement Strategies

Speakers
Jim Turner, Sunrise Labs Director of Software Development
Vicki Anastasi, Regulatory Consultant at VJA Associates
Justin Kelly, RN, Regional VP of Health Policy, at Novocure

Moderator
Brian Johnson, President of MassMedic

Speakers

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Brian Johnson
President
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Today's topics

Challenges and opportunities for risk mitigation of home use devices, life cycle management, and special considerations related to Telemedicine and Cybersecurity

Claims being made about the device being developed, device classification and special considerations or implications related to EUA (Emergency Use Authorization) both near term and longer term

Coverage, Coding and payment opportunities, identifying potential reimbursement barriers and use of clinical evidence to secure coverage

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Jim Turner
Sunrise Labs

Director of Software Development

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Risk Mitigation for Home Use Devices

Challenges

Opportunities

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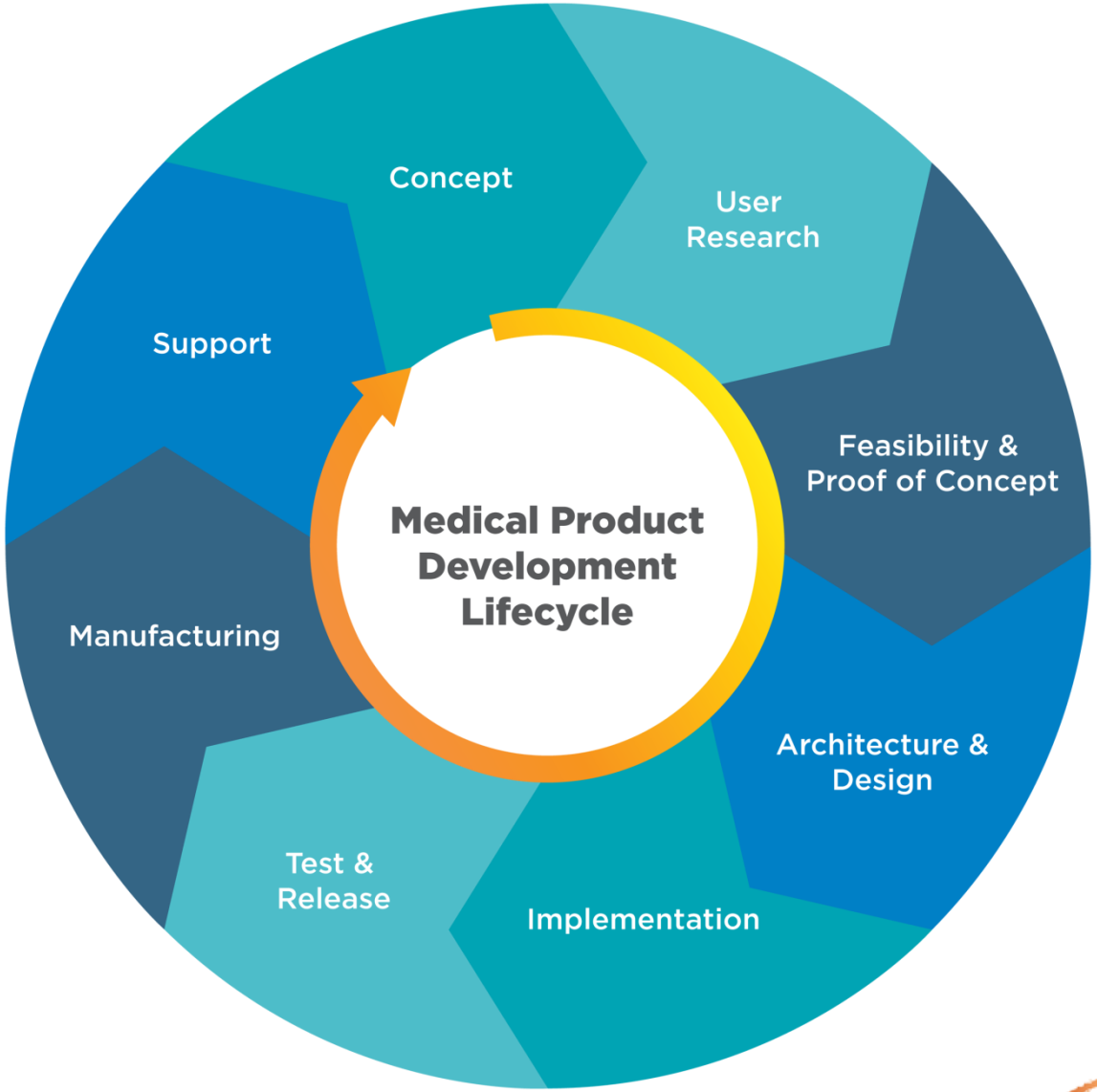
Life Cycle Management

Life cycle in medical devices

Software upgrades

Recalls



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Special Considerations

HIPAA

Cybersecurity

Telemedicine

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Vicki Anastasi
VJA Associates

Regulatory Consultant

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Claims

FDA defines a Home Use Device as a medical device intended for users in any environment outside of a professional healthcare facility. It includes devices intended for use in the home. The user is a patient, caregiver, or family member that directly uses or provides assistance in the use of the device.

Home Use Device claims vary significantly from simple well understood tests (pregnancy, glucose monitoring, etc.) to more complex Infusion pump systems.

As the population continues to age and technology advances more devices are available at home for diagnosis, treatment and monitoring.

As with any medical device, all claims must be verified by testing including critical human factors studies.

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Device Classification

Home Use Devices are as diverse as non home use devices – all classes of devices are regulated for use in the home. It is critical to assess your device to determine the required pathway and corresponding testing plans.

Software is a key component for Home Use Devices.
Minor, Moderate and Major are the categories.

Additionally, Software as a Medical Device is now a key aspect of Home Use Devices.

All aspects of the road to market are dependent on the correct classification of your device inclusive of software.

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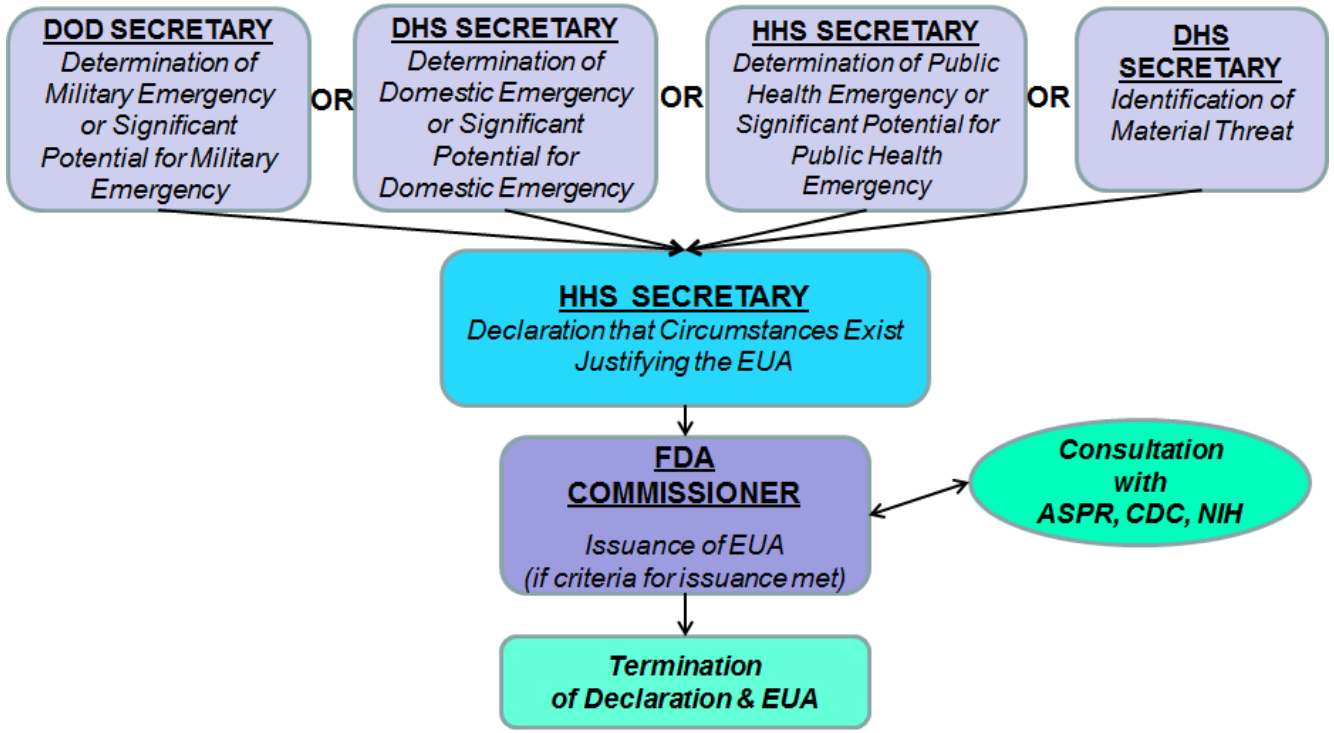
Emergency Use Authorizations

FDA has in place Emergency Use Authorization since 2017.

Recently there is more attention on EUAs due to COVID-19.

It is expected in the next 12 months that more devices/diagnostics and therapeutics will become available for diagnosis and treatment of COVID-19 via the EUA pathway.

Future use of EUA will depend on the need and also the review of the data of the products made available via EUA.



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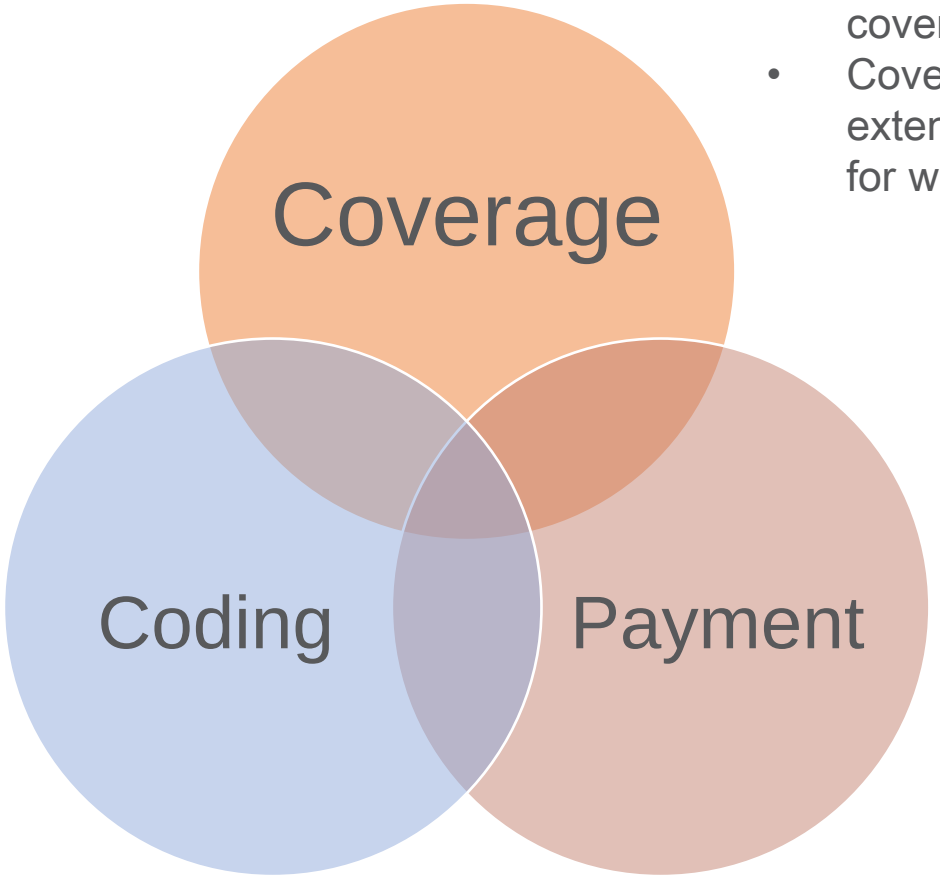
Reimbursement Vocabulary



- Strength of clinical data drives coverage
- Coverage defines the range and extent of services and products for which the insurer will pay

- Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes

- CMS has multiple ways to price HCPCS codes including comparisons to other devices or using contracted rates with commercial carriers

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Durable Medical Equipment Criteria

For an item to be eligible for coverage under the Medicare Durable Medical Equipment (DME) Benefit, specific criteria must be met. 42 CFR 414.202 provides the definition of durability:

1. Can withstand repeated use
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years
3. Is primarily and customarily used to serve a medical purpose.
4. Generally, is not useful to an individual in the absence of an illness or injury
5. Is appropriate for use in the home

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Durable Medical Equipment Pricing Mechanisms

Gap Filling

- Comparison products
- Deflation to 1986 and using CPI-U to calculate fees

Innovative Payment Model for New Home Use Devices

- Uses median commercial contracted rates
  - Only available for new devices that are truly novel and gap-filling using comparison products is not available.

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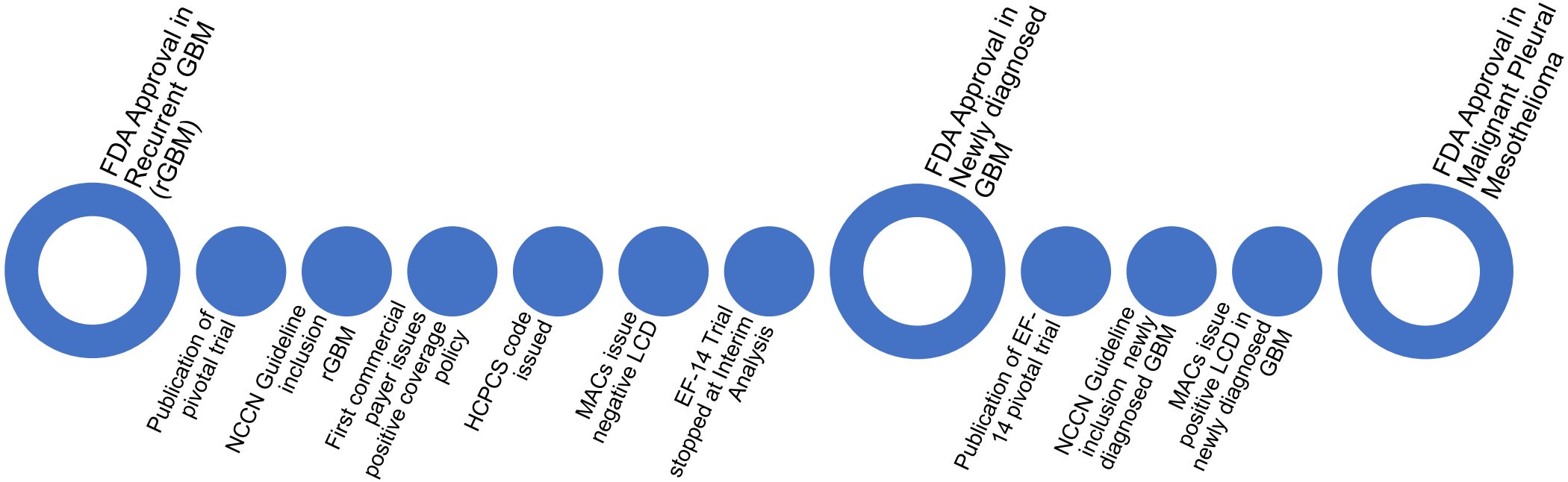
Optune Reimbursement Milestones



Q & A

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Thank You!

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