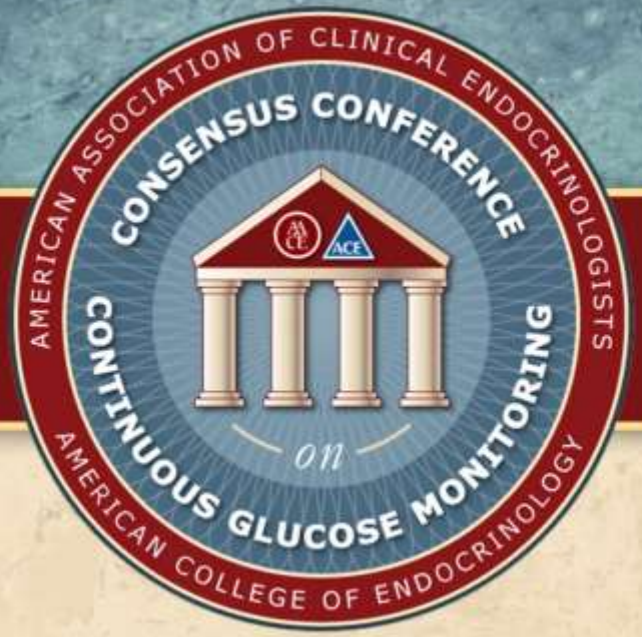


AACE/ACE Consensus Conference on Continuous Glucose Monitoring

February 20, 2016

HYATT REGENCY AT CAPITOL HILL | WASHINGTON, DC

QUESTION 4. WHAT CLINICAL DATA ARE CURRENTLY AVAILABLE TO SUPPORT EXPANDED CGM COVERAGE BY PAYERS AS PERTAINS TO QUESTIONS 1 AND 3? WHAT ADDITIONAL DATA ARE NEEDED?

Question 4a. What data are available to support expanded CGM coverage for professional CGM and patient types by payers as pertains to Questions 1-3? What additional data are needed?

- Clinical effectiveness of professional CGM varies, but some studies show reductions in A1C and hypoglycemia as well as improved patient motivation, especially those with Type 2 Diabetes
- Advantages of professional CGM
  - Greater affordability (intermittent use)
  - Minimal patient education, training, and setup
  - Use of the same transmitter for multiple patients in a professional environment
- More studies are needed to verify the utility of professional CGM

See Notes view for citations

Question 4a. What data are available to support expanded CGM coverage for professional CGM and patient types by payers as pertains to Questions 1-3? What additional data are needed?

- Evidence must demonstrate sustained changes resulting in better QOL and fewer costly complications
- Opinion of the Pillar - Professional CGM has no place in day-to-day diabetes management; all patients wearing CGM should have access to the data
  - Patients improve outcomes (lower A1c, less hypos) by learning from these devices in real time
- Blinded CGM is justified and useful in clinical trials

Question 4a. What data are available to support expanded CGM coverage for professional CGM and patient types by payers as pertains to Questions 1-3? What additional data are needed?

- Personal CGM – un-blinded or real time
- Other definitions are blinded or retrospective

Question 4a. What data are available to support expanded CGM coverage for professional CGM and patient types by payers as pertains to Questions 1-3? What additional data are needed?

- Already answered
- Should avoid the use of term “blinded CGM”
  - Continuous vs intermittent use of CGM
  - Personal vs Professional use of CGM

Question 4b. **What data are available to support expanded CGM coverage for personal CGM and patient types by payers as pertains to Questions 1-3?** What additional data are needed?

- See answers to 1a
- Further studies in the impact of sensor augmented pump systems with threshold suspends with predicted low glucose suspend to reduce the frequency of severe hypoglycemic events.
- The long-term efficacy and safety of close glucose delivery systems.
- Data to support CGM coverage by Medicaid and Medicare for patients.

Question 4b. What data are available to support expanded CGM coverage for personal CGM and patient types by payers as pertains to Questions 1-3? **What additional data are needed?** Cont.

- No Response

Question 4b. **What data are available to support expanded CGM coverage for personal CGM and patient types by payers as pertains to Questions 1-3?** What additional data are needed?

- A wealth of data support personal CGM (see Q1a for references)
- Evidence must demonstrate sustained changes resulting in better QOL and fewer costly complications
- Subgroups more data needed
  - T2D
  - Data in elderly patients
  - Medically underserved
  - Lower economic and literacy levels

Question 4b. What data are available to support expanded CGM coverage for personal CGM and patient types by payers as pertains to Questions 1-3? **What additional data are needed?** Cont.

- No Response

Question 4b. **What data are available to support expanded CGM coverage for personal CGM and patient types by payers as pertains to Questions 1-3?** What additional data are needed?

- Already answered

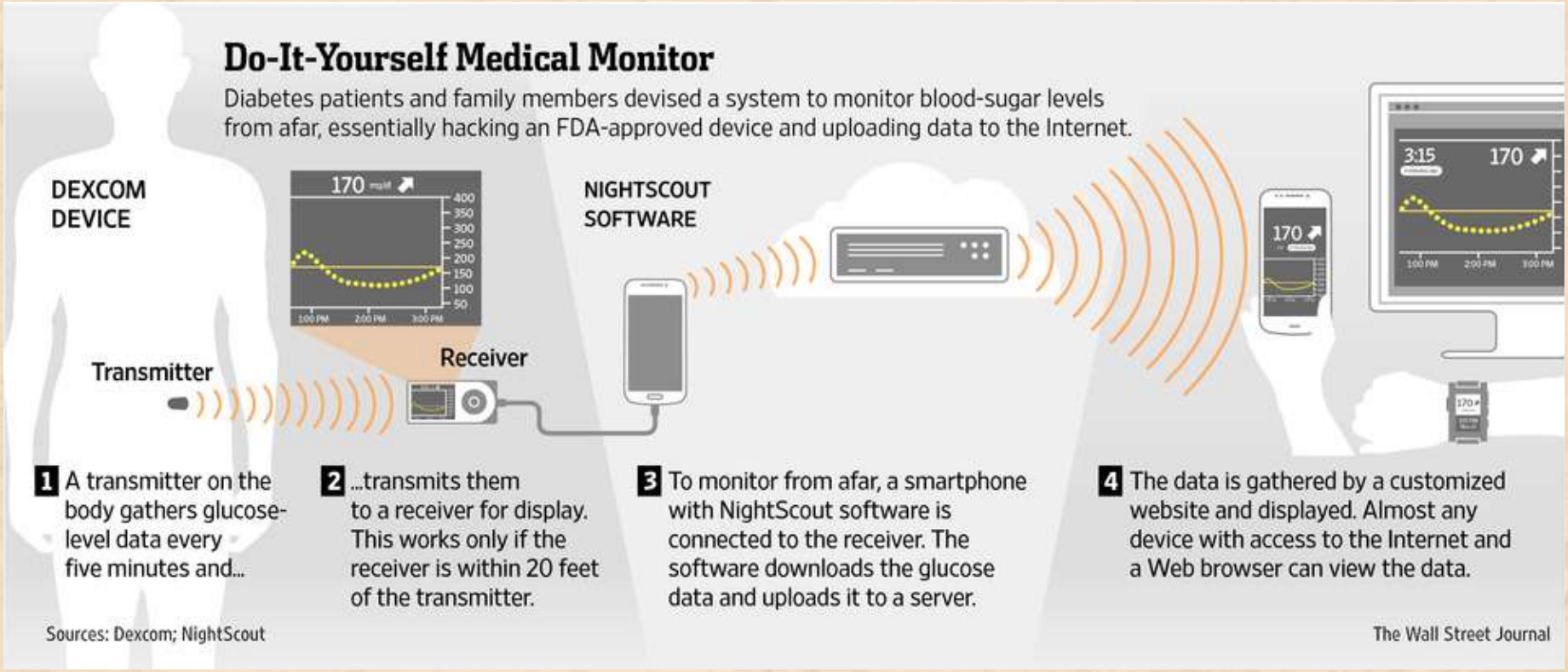
Question 4c. What data are available to support expanded CGM coverage for other types of CGM and patients by payers as pertains to Questions 1-3? What additional data are needed?

- No Response

Question 4c. What data are available to support expanded CGM coverage for other types of CGM and patients by payers as pertains to Questions 1-3? What additional data are needed?

- Addressed in other questions

Q. 4c – Cont. Example of Remote Monitor



Question 4c. What data are available to support expanded CGM coverage for other types of CGM and patients by payers as pertains to Questions 1-3? What additional data are needed?

- No Response

Question 4c. What data are available to support expanded CGM coverage for other types of CGM and patients by payers as pertains to Questions 1-3? What additional data are needed?

No reponse

Question 4d. What other clinical needs would CGM need to address to improve blood glucose self-management and patient engagement for both clinical and economic outcome improvements? Who would be the target patient audience the data support? Do some patient types need further study?

- Improved real-time accuracy
  - False alarms and unreliable results due to glycemic lag
  - Need CGM techniques for precise and specific glucose detection
  - Improved signal-to-noise ratio and sensitivity
- Improved ease of use and wearability
  - Alarm volume
  - Quality of processed data (actionable results)
  - Reduction or obviation of calibration warm-up periods
  - Wearable CGMS
- Special Populations
  - Pediatrics (especially use in children under 8 years old)
  - Geriatrics

Continued

Question 4d. What other clinical needs would CGM need to address to improve blood glucose self-management and patient engagement for both clinical and economic outcome improvements? Who would be the target patient audience the data support? Do some patient types need further study? Cont.

- Device cost
- Ability to dose bolus insulin from CGM rather than SMBG
- Smartphone apps
- Closed loop systems
- Improved reimbursement, especially Medicare

Question 4d. What other clinical needs would CGM need to address to improve blood glucose self-management and patient engagement for both clinical and economic outcome improvements? Who would be the target patient audience the data support? **Do some patient types need further study?** Cont.

- Pregnancy
- Adult and adolescent T2D
- Prediabetes
- Inpatients
- Adolescents
- Non-insulin using T2D
- Impact of CGM errors and deviations on quality of glycemic control and outcomes (Kovatchev 2015)
- Patients undergoing procedures where short-term glycemic variability may increase procedure complications
- Patients at risk for hypoglycemia

See Notes view for citations

AACE/ACE CGM Consensus Conference: Patient/Lay Organizations

Question 4d. What other clinical needs would CGM need to address to improve blood glucose self-management and patient engagement for both clinical and economic outcome improvements? Who would be the target patient audience the data support? Do some patient types need further study?

- Economic measures should be documented, including costs/savings associated with workplace disruption, especially in employer funded healthcare environment
  - Studies showing productivity improvement would demonstrate value of increased spending on devices
- Improved CGM accuracy so the data could be used to determine insulin doses would be a vital step forward
- Studies showing reduction of hypoglycemia unawareness
- MDI – Type 1 and Type 2

Question 4d. What other clinical needs would CGM need to address to improve blood glucose self-management and patient engagement for both clinical and economic outcome improvements? Who would be the target patient audience the data support? Do some patient types need further study?

- Impact of CGM on diabetes in older adults
- CGM use in pregnancy, gestational diabetes
- Hypoglycemia unawareness
- Studies should be sufficiently large and have sufficient duration to document evidence in all patient groups/indications

Question 4d. What other clinical needs would CGM need to address to improve blood glucose self-management and patient engagement for both clinical and economic outcome improvements? Who would be the target patient audience the data support? Do some patient types need further study?

- Kidney failure
- Patients over 65
- GDM

Question 4d. What other clinical needs would CGM need to address to improve blood glucose self-management and patient engagement for both clinical and economic outcome improvements? Who would be the target patient audience the data support? Do some patient types need further study? Cont.

Evidence/Recommendation

- Improved user friendliness should lead to broader adoption, including:
  - Increased accuracy, especially a reduction in false alarms and failure to alarm
  - Longer survival of insertions/sensors
  - Possibly the elimination of insertion by the patient (e.g., a sensor inserted subcutaneously every 6-12 months via a minor outpatient procedure)
- Clinical trials on subjects with recurrent hypoglycemia who represent a significant use of healthcare resources are needed. Significant impacts on reducing healthcare costs are possible in this population

AACE/ACE CGM Consensus Conference: Medical, Scientific, Professional, and Educational Societies

Question 4e. In view of recent scientific evidence and progress in CGM technology, what are the current gaps in CGM reimbursements? The technology itself? Clinician time supervising CGM? In what priority should these gaps in reimbursement be addressed?

- Defer to the Industry Pillar
- Reimbursement barriers for CGM (eg, Medicare, Medicaid, T2D)
  - Medicare reimbursement is highest priority
- FDA perception of CGM as adjunctive to SMBG
- Affordability of the devices (high deductibles from private insurers)
- Unreasonable/unnecessary reimbursement criteria (eg, documentation of BG<50 mg/dL and 4X daily SMBG recordings before and after starting CGM)
- CGM supervision and especially time needed for data interpretation should be reimbursed for all qualified HCPs (CDEs, not just MDs and NPs)
- Structured education for patients

AACE/ACE CGM Consensus Conference: Patient/Lay Organizations

Question 4e. In view of recent scientific evidence and progress in CGM technology, what are the current gaps in CGM reimbursements? The technology itself? Clinician time supervising CGM? In what priority should these gaps in reimbursement be addressed?

- Gaps
  - Reimbursement barriers for CGM (eg, Medicare, Medicaid)
  - Medicare reimbursement is priority #1
  - Affordability of the devices (high deductibles from private insurers)
- CGM supervision should be adequately reimbursed
  - Patients rely on HCP review of data to help them
  - HCPs often review data independent of patient visits and reimbursement should be structured to compensate for this time

Question 4e. In view of recent scientific evidence and progress in CGM technology, what are the current gaps in CGM reimbursements? The technology itself? Clinician time supervising CGM? In what priority should these gaps in reimbursement be addressed?

- Reimbursement of technology and of HCPs' time are equally important
- Determine reimbursement rates for CPT code 95251, interpretation and report of CGM data
- Only payable if not done more often than once a month

Question 4e. In view of recent scientific evidence and progress in CGM technology, what are the current gaps in CGM reimbursements? The technology itself? Clinician time supervising CGM? In what priority should these gaps in reimbursement be addressed?

- Gaps in technology reimbursement include:
  - No Medicare reimbursement of personal CGM
  - No commercial reimbursement of personal CGM for most T2D patients
  - Lack of ease of reimbursement for personal CGM for T1D patients (prior authorization)
- To close reimbursement gaps, CGM costs should be reduced and legislation passed to cover Medicare patients for personal CGM
- Need additional codes for professional CGM as this technology becomes more sophisticated