DIABETES MELLITUS TYPE I OR TYPE II - INSULIN TREATED CGM OPTION

C. CERTIFICATION AID

(Updated 08/30/2023)

The following are the specifics of the ITEM numbers listed in the Initial and Renewal requirements:

ITEM #1: INITIAL COMPREHENSIVE REPORT (Updated 03/30/2022)

INITIAL COMPREHENSIVE in-person evaluation performed within the **past 90 days** from the treating **board-certified endocrinologist.** The individual must submit a copy of the **actual comprehensive current, detailed Clinical Progress Note. (We will NOT accept the patient encounter summary or a letter from the endocrinologist.)** It must detail and comment on **ALL** of the following[*1]:

A. DIABETES HISTORY:

1. Characteristics at onset (age, symptoms, etc.):
    a) Review previous treatment and response
    b) Frequency/cause/severity of past hospitalizations
    c) Complications and common comorbidities:
        - Any end organ damage (macrovascular or microvascular);
        - Presence of hemoglobinopathies or anemias;
        - High blood pressure or abnormal lipids and treatment; and
        - Visits to specialist (what type and why)
    d) Lifestyle and behavior patterns:
        - Eating patterns and weight history;
        - Sleep behavior and physical activity;
        - Familiarity with carbohydrate counting, if applicable;
        - Tobacco, alcohol, and substance use; and
        - Any motor vehicle accidents or incidents pertinent to their history of diabetes
2. Medication and Reporting:
    a) Medication compliance;
    b) Medication intolerance or side effects;
    c) Complementary or alternative medicine use;
    d) Glucose monitoring (meter/CGM) results and data use; and
    e) Review insulin pump settings
3. Screening for Psychosocial conditions:
    a) Screen for depression, anxiety, disordered eating (ex: Patient Health Questionnaire 9 or 2 [PHQ-9 or PHQ-2] or similar);
    b) Cognitive impairment assessment (and formal testing, if clinically indicated); and
    c) Diabetes self-management education and support:
        - History of dietician/diabetes educator visits; and
        - Screen for barriers to diabetes self-management
4. Glucose control:
    a) **HYPO**glycemia:
        - Any symptomatic episodes in the **past 12 months** requiring treatment or assistance by another individual, with comment on timing, awareness, frequency, causes, and treatment.
        - Sustained episodes, e.g., CGM/FSBG values below 70 mg/dL for over 30 minutes or below 54 mg/dL for over 15 minutes, with comment on symptoms and treatment.
    b) **HYPER**glycemia:
        - Any symptomatic episodes in the **past 12 months** with comment on timing, awareness, frequency, causes, and treatment.
        - Sustained episodes (e.g., CGM/FSBG values above 250 mg/dL for over 60 minutes or above 300 mg/dL for over 30 minutes) with comment on symptoms and treatment.

B. PHYSICAL EXAM (Must narrate what is examined and any findings):

1. Height, Weight, Body Mass Index (BMI);
2. Pulse and blood pressure including orthostatic blood pressure, when indicated;
3. Thyroid palpation and skin exam (acanthosis nigricans, insulin injection or insertion sites, lipodystrophy); and
4. Comprehensive foot exam:
    a) Visual inspection; screen for PAD (check pedal pulses; refer for ABI if diminished); and
    b) Determination of temperature, vibration or pinprick sensation, and 10-g monofilament exam

C. ASSESSMENT AND PLAN:

1. Current status of diabetes including an assessment of **compliance**, **glucose control,** and **stability** as well as their ability to monitor and respond accordingly to HYPO and HYPER glycemic events and administer insulin doses;
2. Prognosis for progression over the next 12 months; and
3. Recommendations for treatment changes

D. DATE OF NEXT CLINICAL FOLLOW-UP (Required every 3 months for FAA.)

*1 Modified from American Diabetes Association (ADA) Standards of Medical Care 2020

ITEM #2: LAB

LAB - Initial/Annual comprehensive panel **performed within the past 90 days:**

A. A1C	Within last 90 days AND all prior values from the preceding 12 months
B. CBC	Complete Blood Count
C. Lipids	Total, LDL [low density lipoprotein], HDL [high density lipoprotein], cholesterol, and triglycerides
D. LFT's	Liver function tests
E. Microalbumin	or spot urinary albumin-to-creatinine ratio
F. Renal function	Serum creatinine, BUN (blood urea nitrogen), eGFR (estimated glomerular filtration
G. TSH	Thyroid-stimulating hormone
H. Vitamin B12	When clinically indicated
I. Potassium	Serum level when clinically indicated or when taking ACE-I (angiotensin converting enzyme inhibitors), ARBs (angiotensin II receptor blockers), or diuretics

ITEM #3: CONTINUOUS GLUCOSE MONITOR (CGM) DATA (Updated 08/30/2023)

When submitting CGM data:

- ☐ **DO** Submit the required weekly or monthly graphs. (See examples on the following pages)
- ☐ **DO NOT** submit daily or hourly statistics from insulin pumps.
- ☐ When providing CGM Data reports, for each month of data, include the following reports based on your device. **Submit the original digital reports IN COLOR** (when possible):

DEXCOM

- ☐ Overview Report
- ☐ Ambulatory Glucose Profile (AGP) Report
- ☐ Alert Settings
- ☐ Weekly Overlays/Graphs (for each week of the month)

MEDTRONIC

- ☐ Assessment & Progress Report
- ☐ Weekly Overlays/Graphs (for each week of the month)

OTHER DEVICES

- The data report should include estimated A1c (and/or glucose management indicator [GMI]), average glucose, coefficient of variation, standard deviation, time in range, sensor usage, and weekly overlays/graphs.

A. CONTINUOUS GLUCOSE MONITOR (CGM) DATA on a device that meets the FAA's minimum CGM device feature requirements.

1. Readings from (at a minimum) the preceding **6 months for initial certification** and thereafter 3 months.
2. Analyze to identify **percentage time** in the following ranges:
   a) Less than 54 mg/dL
   b) Less than 70mg/dL
   c) Between 70 and 180 mg/dL
   d) Above 180 mg/dL
   e) Above 250 mg/dL

B. CGM DEVICE FEATURES: The FAA does not endorse any particular manufacturer, however, the CGM device **must** have the following features:

1. Must be **FDA-approved** and **appropriate for age**;
2. Must be a real-time CGM (automatically transmits glucose data to the user) without need to manually scan the sensor (e.g., intermittently scanned CGM);
3. Have **"predictive arrow trends"** that provide warnings of potentially dangerous glucose levels (high or low) before they occur;
4. Able to **customize** low and high glucose levels;
5. Have a high-accuracy rating with an overall Mean Absolute Relative Difference (MARD) of 10% or less. (e.g., If the MARD is 10% and the glucose reading is 70mg/dL, the actual blood glucose could be as low as 63 mg/dL or as high as 77mg/dL);
6. Printout reports must include monthly summary showing: **Time-In-Range (TIR) Values for 70-180 mg/dL; Average Glucose Levels; Standard Deviation (SD);** and (when provided by the reporting software) **Coefficient of Variability [CoV]** values. **Reports must include weekly glucose value data graphics**. **All data must be legible.** Failure to provide these values could result in a **delay** in processing your application;
7. Calibrated to at least at the minimum frequency required by the manufacturer or endocrinologist; and
8. Must be individual's own, **unblinded CGM** t**hat cannot be shared** with anyone else. The individual cannot use anyone else's CGM (e.g., blinded CGM device, which is professional use only).
   a) **Time-In-Range (TIR) Values** for 70-180 mg/dL;
   b) **Average Glucose Levels**;
   c) **Standard Deviation (SD**); and (when provided by the reporting software)
   d) **Coefficient of Variability [CoV]** values;
   e) Alarm Settings, indicating both high and low alarms are active;
   NOTE: CGM Alarm Settings and Repeat Alarm Settings should be turned ON.
   f) **Device manufacturer and current mode**l; and
   g) **Reports must include weekly glucose value data graphics. All data must be legible**. Failure to provide these values could result in a **delay** in processing of the application.

CGM devices that currently meet the required features (as of 08/30/2023**)** include:

Dexcom G7
Dexcom G6
Dexcom G5
Dexcom G4 PLATINUM
Freestyle Libre 3
Medtronic MiniMed 670G system CGM with insulin pump
Medtronic MiniMed 630G system CGM with insulin pump
Medtronic Guardian Connect CGM system
Senseonics' Eversense CGM (90-day monitor)
Senseonics' Eversense E3 CGM (180-day monitor)

This list may not be all-inclusive. Refer to the CGM Device Features in **Item B**.

C. INSULIN PUMP REQUIREMENTS:

1. If using an insulin pump, it must have the ability to suspend insulin for a predictive low glucose or predicted pressure changes;
2. Insulin used in the pumps must be FDA approved for that use; and
3. Insulin pumps must also be FDA approved as compatible with the CGM device. (Not all CGM devices are compatible with all insulin pumps.)

ITEM #4: EYE EVALUATION

EYE EVALUATION performed within the past 90 days from a **board-certified ophthalmologist** (M.D. or D.O.). Exam by optometrist (O.D.) is **NOT** acceptable. Evaluation must include:

A. VISUAL ACUITY (with and without correction) each eye separately and together for:
1. Near;
2. Intermediate; and
3. Distance vision

B. EVALUATION FOR OTHER RETINAL OR CLINICALLY SIGNIFICANT EYE DISEASE:
1. Cataracts, any evidence;
2. Color vision deficiency: test used; method used;
3. Contrast sensitivity: test used; method used;
4. Depth perception abnormality;
5. Intra Ocular P Pressure (IOP) reading (and treatment if required): test used, method used; and
6. Visual field defects: type of test, method used (confrontation fields are acceptable).

C. DILATED FUNDUS EXAM with documentation of absence of retinopathy or degree of retinopathy, if present, and any treatment indicated or recommended.

D. DIAGNOSIS, PROGNOSIS, AND RECOMMENDATIONS FOR TREATMENT OR FOLLOW-UP.

ITEM #5: CARDIAC RISK EVALUATION (Updated 08/30/2023)

CARDIAC RISK EVALUATION performed within the past 90 days from a **board-certified cardiologist (M.D. or D.O.), not a mid-level practitioner.** The document submitted MUST be from the actual in-person office evaluation and resultant current, detailed Clinical Progress Note**:**

A. INITIAL CARDIAC RISK EVALUATION:
1. Evaluation from a board-certified cardiologist assessing cardiac risk factors;
2. Baseline ECG (regardless of age);

3. The **evaluation must be COMPREHENSIVE, in-person, and performed** within the **past 90 days** from the treating **board-certified cardiologist.** The individual must submit a copy of the **actual comprehensive current detailed Clinical Progress Note. (We will NOT accept the patient encounter summary** [after visit summary] **or a letter.)**

B. STRESS TEST (Maximal exercise treadmill stress testing (Bruce)**:**

1. Beginning at age 40,
2. every 5 years thereafter, and
3. at any age when clinically indicated**:**
   See Graded Exercise Stress Test Protocol.

C. IF THERE ARE ANY ABNORMALITIES on the ECG, stress test, or identification of any cardiac conditions, the cardiologist must provide a report that details:

1. Any confirmed or suspected diagnosis
2. Clinical status including any symptoms
3. Control of cardiac risk factors (HTN, smoking, hyperlipidemia, exercise, weight)
4. Treatment or monitoring required or recommended and any side effects
5. Were other investigations conducted or recommended (attach reports)
6. Risk of any acutely disabling cardiovascular event (annualized percentage risk)

For information on how to send documents to the FAA, see How to Submit Documents for Initial or Recertification/Renewal.