DIABETES MELLITUS TYPE I OR TYPE II
INSULIN TREATED - CGM OPTION
INITIAL CERTIFICATE CONSIDERATION REQUIREMENTS:

(Updated 03/30/2022)

For consideration for first- or second-class airman certification, the airman must submit Continuous Glucose Monitoring (CGM) data. Below is a list of requirements. For details of what specific information must be included for each requirement/report (ITEMS #1-5), see the following pages.

The airman must demonstrate stability and adequate control, verified by CGM data, for a minimum of 6 months. Airman with a new diagnosis of Insulin-treated Diabetes Mellitus (ITDM) or any concerns regarding their control may require a longer stability period.

Submit the following **performed within the past 90 days**:

ITEM # 1 Initial Comprehensive clinical consultation from your treating board-certified endocrinologist. This may be labeled progress note, consultation note, or history and physical. Note: For initial evaluations, the former DIABETES ON INSULIN Re-Certification STATUS REPORT (Now called "Diabetes on Insulin Re-Certification Status Report NON CGM – Third Class Option") will **NOT** be accepted. The Initial Comprehensive Report contains significant additional information.

ITEM # 2 Lab - Initial/Annual comprehensive panel;

ITEM # 3 **Monthly** CGM data with a device that meets FAA requirements for the preceding 12 months (when available) in **overlay view**.
It should show trends per day of actual readings, not only averages.

It should show trends per day of actual readings, not only averages.
If recently started on CGM, a minimum of 6 months of CGM data is required for consideration. CGM data should demonstrate consistent, effective ongoing use; time-in-range (80–180 mg/dL); and excursions below 54, below 70 and above 180, and above 250 mg/dL. (See chart below.)

Parameter	Target Range for Certification Consideration
Auto Mode	Greater than 90%
Coefficient of Variance	Less than or equal to 33% (May consider up to 36%.)
Glucose Management Indicator (GMI)	Less than 6.5%
Glucose readings - less than 54 mg/dl	less than 1%
Glucose readings - less than 70 mg/dl	less than 4%
Glucose readings - greater than 250 mg/dl	less than 5%
Overall glucose readings - 70-250 mg/dl	90% or greater
Sensor wear	90% of the time or greater
Time in Range (TIR) of 80-180 mg/dl	70% or greater

ITEM # 4 **Eye evaluation** from a board-certified ophthalmologist (M.D. or D.O.). Exam by optometrist (O.D.) is **NOT** acceptable; AND

ITEM # 5 **Cardiac Risk Evaluation** from a board-certified cardiologist

Additional information may be required on a case-by-case basis.

When your AME performs your exam (8500-8), they must DEFER. Work with your Aviation Medical Examiner (AME) to coordinate submission of all of the above documents to the FAA for consideration. Mail to:

Using Regular Mail (US Postal)	or	Using Special Mail (FedEx, UPS, etc.)
Federal Aviation Administration Aerospace Medical Certification Division CAMI Building 13, Room 308, AAM-300 P.O. Box 25082 Oklahoma City, OK 73125		Federal Aviation Administration Aerospace Medical Certification Division 6500 S. MacArthur Boulevard CAMI Building 13, Room 308, AAM-300 Oklahoma City, OK 73169

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

ITEM #1: INITIAL COMPREHENSIVE REPORT (Updated 09/30/2020)

INITIAL COMPREHENSIVE in-person evaluation performed within the **past 90 days** from the treating **board-certified endocrinologist.** The airman 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 - 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: comment on
    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 the airman's **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.	**Micro albumin**	(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 03/30/2022)

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 every 30 days (submit these monthly summaries to the FAA as one combined package every 6 months).
2. Analyze to identify **percentage time** in the following ranges:
   a) Less than 54 mg/dL
   b) Less than 70mg/dL
   c) Between 80 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 airman's 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 **automatic alarms, automatically transmitted** to receiver, for notification of high or low glucose readings with at least two of the following: audio, visual, or tactile;
4. Have **"predictive arrow trends"** that provide warnings of potentially dangerous glucose levels (high or low) before they occur;
5. Able to **customize** low and high glucose levels;
6. 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);
7. Calibrated to at least at the minimum frequency required by the manufacturer or endocrinologist;
8. Ability to use sensor according to manufacturer specifications; and
9. Must be airman's own, **unblinded CGM** t**hat cannot be shared** with anyone else. Airman cannot use anyone else's CGM (e.g. blinded CGM device, which is professional use only).
10. Printout reports must include monthly summary showing: [samples can be found on subsequent pages]
    a.) **Time-In-Range (TIR) Values for 80-180 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;**
    f.) **Device manufacturer and current model; 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 your application.

CGM devices that currently meet the above CGM Device Features (as of 03/30/2022) include:
Dexcom G6
Dexcom G5
Dexcom G4 PLATINUM
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 above.

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 an optometrist (O.D.) is **NOT** acceptable. The document submitted MUST be the actual in person office evaluation and resultant detailed clinical progress note. 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/or
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 03/30/2022)

CARDIAC RISK EVALUATION performed within the past 90 days from a **board-certified cardiologist.** The document submitted MUST be the actual in person office evaluation and resultant detailed clinical progress note**:**

A. INITIAL EVALUATION AND ANNUALLY:

1. Evaluation from a board-certified cardiologist assessing cardiac risk factors; and
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 airman must submit a copy of the **actual comprehensive current detailed Clinical Progress Note. (We will NOT accept the patient encounter summary or a letter.)**

B. EVERY 5 YEARS AND AS CLINICALLY INDICATED:

1. Maximal exercise treadmill stress testing (Bruce): beginning at age 40 and every 5 years thereafter and 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)