

Service Area: Patient Services	YALE NEW HAVEN HEALTH POLICY & PROCEDURES	
Title: Continuous Subcutaneous Insulin Infusion Pump and / or Continuous Glucose Monitoring - Patient Self-Management While Admitted and Usage During Radiology Exams		
Date Approved: October 2019	Approved by: Formulary Integration Committee (FIC) and System Clinical Council	
Date Effective:	Date Reviewed/Revised: Sept 2020	
Distribution: MCN Policy Manager	System Policy Type (I or II): I	
Supersedes:		

PURPOSE

To provide guidance for inpatients to safely self-manage their own care Continuous Subcutaneous Insulin Infusion Pump (CSII or Insulin Pump) and/or Continuous Glucose Monitoring (CGM) systems.

APPLICABILITY

This policy applies to each licensed hospital affiliated with Yale New Haven Health System (YNHHS), including Bridgeport Hospital, Greenwich Hospital, Lawrence + Memorial Hospital, Westerly Hospital, Yale New Haven Hospital and any other hospital that may affiliate with YNHHS.

DEFINITIONS

CSII / Insulin pump: An external continuous infusion device used to deliver a constant infusion of rapid-acting insulin (pre-set basal insulin rates) and patient-delivered pre-meal boluses and correction boluses of insulin to manage glycemic control.

Continuous Glucose Monitoring (CGM) systems use a small “sensor” inserted subcutaneously to continuously measure glucose levels in interstitial fluid. Results from the sensor are transmitted to a “receiver” device (which at times can be a smart phone), which displays real-time glucose levels and glycemic trends.

Automated Insulin Delivery Insulin Pump system is interfaced with CGM, which alters basal insulin delivery in response to trajectories and absolute concentrations of interstitial glucose. Importantly, patients will still need to bolus for carbohydrate intake and may need to administer correction doses of insulin.

- **Low suspend and predictive low glucose suspend systems (examples include the t:slim X2™ with Basal-IQ™, Medtronic 530G, Medtronic 630G):** Interrupt basal insulin delivery either in response to a low sensor glucose value or a predicted low sensor glucose value.
- **Hybrid Closed Loop (HCL) insulin pumps (examples include Medtronic 670G and the t:slim X2™ with Control-IQ™):** Systems with the capacity to both increase or reduce basal insulin delivery based on sensor glucose values.

POLICY

- A. The admitting provider evaluates if the patient or identified caregiver (significant other (SO), parent, guardian) is capable of self-management of the insulin pump and/or CGM system.
- B. The patient's insulin pump settings (i.e., basal-bolus settings) may require adjustment during hospitalization to prevent, or at least minimize, hyper- and hypoglycemia, including but not limited to:
 - a. Stress of illness, infection, surgery
 - b. Alterations in carbohydrate intake
 - c. Enteral or parenteral nutrition
 - d. Administration of medications that may alter glycemic control (e.g., steroids, pressors, octreotide, etc.)
- C. Adjustments to the insulin pump settings are ordered by the provider.
- D. The patient maintains and adjusts the settings for his/her insulin pump per provider order.
- E. If surgery is planned, the anesthesiologist and the patient will collaborate on the use of the insulin pump and/or CGM in the perioperative period.
- F. CGM is not FDA-approved to guide inpatient hospital therapy. However, CGM is sometimes paired to the insulin pump, and therefore may be useful in informing self-care.

PROCEDURE

Continuous Subcutaneous Insulin Infusion (CSII / Insulin) Pump

1. The provider will verify that the patient wishes to maintain control of their medical condition by continuing on his/her insulin pump during the hospital stay and is able to participate in self-care.
2. The provider will confirm the patient's (or caregiver's) ability to manage the insulin pump including:
 - a. Fully alert and oriented to person, place and time
 - b. Manual dexterity to manage insulin pump and infusion set changes
 - c. Visual acuity sufficient to properly read the pump screens and device buttons
 - d. Ready access to patient's insulin pump supplies, provided by the patient or family/SO from home
 - e. A signed agreement from the patient for insulin pump management during admission. The signed form is to be placed in the patient's medical record and a copy given to the patient.
3. The provider will assess for potential contraindications to insulin pump management including:
 - a. Patient unable to manage insulin pump due to change in cognition, impaired level of consciousness, manual dexterity or visual limitations.
 - b. Behavioral/self-harm concerns (not an absolute contraindication; psychiatrist to determine)
 - c. Major psychiatric disturbance (not an absolute contraindication; provider to determine)
 - d. Lack of patient-provided insulin pump supplies
 - e. Medical conditions, such as DKA, critical illness
 - f. Insulin pump malfunction
 - g. Other reasons as determined by provider

4. The provider will explain to the patient that the health care team reserves the right to remove the pump from the patient at any time during their stay if it is assessed that the patient is no longer able to manage his/her own care.
5. The provider will make an alternative insulin replacement plan (Basal-Bolus-Correction insulin regimen or insulin infusion order) and allow removal of the insulin pump from the patient in the event the insulin pump is discontinued
6. Nurse to confirm patient-supplied insulin pump supplies are available to support pump use throughout the hospital stay as the hospital does NOT stock these supplies for insulin pumps. There should be enough supplies for scheduled changes and at least one unscheduled site change. These are to be kept at the patient's bedside.
7. Pharmacist to confirm patient-supplied insulin vial(s) as outlined in the [YNHHS Medications Brought into the Organization by Patients or their Families Policy](#). If patient-supplied insulin is not available, provider can order a vial to be supplied by the Pharmacy.
8. Nursing will verify that a provider order exists in the patient's medical record for use of insulin pump in the hospital setting. The order must contain the following:
 - a. To leave insulin pump in place and continue current basal rates and other settings
 - b. Contact information including phone number/pager number of the Clinician who prescribed/manages the insulin pump with the patient
 - c. Manufacturer of insulin pump
 - d. Generic and Brand name of insulin used in the pump as well as concentration
 - e. Basal rate settings including hourly doses with start and stop time.
 - f. Bolus dose parameters for mealtime and correction insulin for off-target glucose readings
 - g. For hybrid closed-loop insulin pump systems only, an indication that the insulin pump is capable of "automated delivery mode" for basal insulin alterations and/or auto-boluses
 - h. Target blood glucose ranges
 - i. Hospital POC glucose testing with associated Hypoglycemia Management orders
 - j. Infusion site change at least every 72 hours
 - i. Infusion site may be changed sooner if inflammation, tenderness, redness, swelling, bleeding of site or blood glucose results greater than 250mg/dL for 2 consecutive readings at least 2 hours apart
 - ii. Point of care blood glucose testing one hour after infusion site change to assess insulin delivery/absorption
 - k. Removal of insulin pump before radiological procedures unless the device manufacturer provides information supporting safe use. If the device cannot be temporarily stopped, see the Appendix for additional information for evaluation of risks and benefits.
 - l. Diet order for consistent carbohydrate
 - m. Consultations as applicable per delivery network:
 - i. Endocrinology (Mandatory to call Pediatric Endocrinology for ALL pediatric patients)
 - ii. Diabetes Clinical Nurse Specialist/Certified diabetes educator (CDE)
 - iii. Registered Dietitian Nutritionist (RDN)
9. Nurse will document the presence of the insulin pump as well as the date of the last infusion set and site change on admission.

10. Nurse will communicate to the patient the POC glucose each time it's performed. Nurse will document in the MAR all patient-administered mealtime bolus and correction doses in real time, which will include the time of administration and the units of insulin given.
11. Nurse will assess and document the location and appearance of the infusion site for signs of inflammation or infection once a shift.
12. Nurse will notify the provider if:
 - a. Blood glucose targets are not consistently maintained
 - b. Any concerns with patient's ability to self-manage their insulin pump
 - c. Patient is unable to change infusion set due to lack of supplies or otherwise unable
13. Provider to notify Radiology Department if patient is scheduled for any radiological procedure involving x-ray/flourosocopy, CT scanning or MRI that the patient utilizes an insulin pump. See Appendix for additional information.
 - a. Provider should order to remove the insulin pump prior to these radiological procedures
 - i. For imaging time less than an hour, the insulin pump may be temporarily disconnected from the patient with no alternate insulin therapy provided
 - ii. For imaging time greater than an hour the provider should consider ordering an alternate form of insulin therapy
 - b. The insulin pump must be kept outside of the room where the diagnostic imaging procedure is being performed
 - c. Infusion sets that contain a metal cannula must be removed by the patient prior to MRI
14. If insulin pump is discontinued due to patient inability to self-manage or other critical medical condition the following must occur:
 - a. Alternate insulin therapy must be immediately ordered (SC or infusion) and initiated
 - b. Insulin pump must be disconnected from the patient
 - c. Insulin pump will be either secured by staff per individual facility policy or sent home with a designated family member/SO

Continuous Glucose Monitoring (CGM) System

1. The provider will confirm the patient's (or identified SO, parent, guardian) ability and understanding for use of CGM in the hospital setting including:
 - a. Fully alert and oriented to person, place and time
 - b. Treatment decisions will be based on hospital point of care blood glucose meter results and not CGM values as CGM is not FDA approved for inpatient glycemic monitoring or management
 - c. CGM results are for patient's own information only
 - d. Manual dexterity to change sensor and calibrate as necessary
 - e. Results from hospital POCT glucose may be used for CGM calibration (as indicated by manufacturer)
 - f. A signed agreement from the patient for CGM monitoring during admission. The signed form is to be placed in the patient's medical record and a copy given to the patient
2. Nurse to confirm patient-supplied CGM supplies are available to support CGM use during admission as the hospital does NOT stock these supplies.

3. Nurse to assess CGM insertion site every shift and document site assessment in flowsheet in EMR.
4. Provider to notify Radiology Department (if/when scheduled for radiological procedures) that the patient is wearing a CGM. CGM manufacturers indicate that CGM must be removed by patient prior to CT scanning or MRI, and device should not be exposed to X-rays. See Appendix for additional information.
5. Consultations as applicable per delivery network:
 - a. Endocrinology (Mandatory to call Pediatric Endocrinology for ALL pediatric patients)
 - b. Diabetes Clinical Nurse Specialist/Certified diabetes educator (CDE)
 - c. Registered Dietitian Nutritionist (RDN)
6. If CGM must be removed because patient is undergoing diagnostic procedures and/or runs out of necessary supplies:
 - a. Sensor & transmitter must be physically removed from the patient.
 - b. CGM transmitter and receiver will either be secured by staff or sent home with designated family member/SO.

Automated Insulin Delivery Insulin Infusion Pump

1. Automatic Mode (algorithm-regulated basal rates) may not be appropriate in all clinical situations. Admitting provider to determine if patient situation is appropriate for the HCL pump to operate in “Automatic Mode”. This must be indicated in the Insulin Pump Order Set.
 - a. At YNH (YSC and SRC), Endocrinologist, Endocrine Fellow or Diabetes Team APRN must be consulted.
 - b. At other delivery networks (BH, GH and LMH/WH), admitting provider, unless absolutely certain, should consult patient’s insulin pump prescriber as applicable.
2. Examples of inappropriate use of automatic mode on admission include, but are not limited to:
 - a. High-dose steroid therapy
 - b. DKA, HHS or critical illness
 - c. Patient without sensor supplies available
 - d. Any sensor issues or malfunctions
 - e. At the discretion of the provider

REFERENCES

1. Improving the Clinical Value and Utility of CGM Systems: Issues and Recommendations A Joint Statement of the European Association for the Study of Diabetes and the American Diabetes Association
2. Diabetes Technology Working Group. Petrie, JR, et al. Diabetes Care, 40 (12): 1614-1621, 2017.
3. International Consensus on Use of Continuous Glucose Monitoring. Danne, T, et al. Diabetes Care. 40 (12): 1631-1640, 2017.
4. American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement. Bailey, TS et al. Endocrine Practice. 22 (2): 231-261. 2016.
5. Diabetes Technology Update: Use of insulin Pumps and Continuous Glucose Monitoring in the Hospital. Umpierrez, GE and Klonoff, DC. Diabetes Care 2018; 41 (8): 1579-1589.
6. American Diabetes Association. Diabetes care in the hospital: Standards of Medical Care in Diabetes 2018. Diabetes Care 2018; 41 (Suppl. 1):S144–S151.

APPENDIX:

The insulin pump or CGM system are to be removed before any radiological procedure involving x-ray/fluoroscopy, CT scanning or MRI unless the device manufacturer provides information supporting safe use. If the device cannot be temporarily stopped, see the below for additional information for evaluation of risks and benefits.

Insulin Pump and CGM Systems during X-ray exams, CT Scans and MRI

- The presence of an insulin pump or glucose monitor should not preclude medically indicated CT or X-ray imaging but device should be removed whenever possible .
 - The probability that x-ray or CT scan irradiation causes a device malfunction and an adverse event is extremely low and even less if the device is not in the region that is being imaged.
 - No known adverse events during CT imaging of insulin pumps or glucose monitors are reported. Other electronic devices such as cardiac implantable electronic devices and neurostimulators have reported possible adverse events but there is little evidence that CT irradiation was the direct cause of these events.
- Standard MRI safety precautions should be followed prior to MRI. Many insulin pumps and glucose monitors are deemed MRI UNSAFE and MUST be removed as there is high potential for device damage and potential patient injury.

Recommendations for Physicians ordering CT scan or X-ray:

Advise patient to remove device during exam. If the device can't be removed or patient refuses, assess if imaging will cover the area over the insulin pump or CGM system and see if system can be safely moved, attached to a different location, turned off and for how long, or if alternative diabetes management is required.

Recommendations for Radiologists and X-ray/CT Radiologic Technologists:

- a. Advise patient to remove device and store it in control room during imaging procedure.
- b. If patient can't remove or refuses to remove device
 - i. Advise patient that device damage is possible and ensure they understand potential risk of damage and agree to proceed with imaging.
 - ii. If system is tethered to a cannula and can be safely moved, work with the patient to move it to avoid direct exposure to the primary x-ray beam
 - iii. If the system cannot be safely moved, ask the patient if it can be safely turned off during the exam. Set a timer and remind the patient to turn their pump back on afterwards and to check it for proper function.
 - iv. If possible, avoid including the insulin pump or CGM system inside the scanning range. Confirm the required anatomic range with the supervising radiologist.
- c. For CT and X-ray procedures where the medical device is located within the programmed scan range and cannot be safely moved or turned off, minimize direct x-ray exposure to the electronics of the infusion pump by following standard ALARA (as low as reasonably achievable) protocol.
- d. Imaging exams that would involve scanning directly over the electronics of the device for more than several seconds (i.e. CT perfusion exams or interventional procedures such as CT fluoroscopy), require additional care and should not be performed unless the device can be safely relocated or turned off. If moving or turning the insulin pump or CGM system off is not possible and the scan is urgently needed, careful monitoring of the device during and after the procedure is required.