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	ORIGINAL ISSUE DATE	CURRENT EFFECT DATE	CATE/DIV	SECT. #	SECT.CODE	POLICY /PROCEDURE/PLAN #
[ ] POLICY [ ] PROCEDURE [X] POLICY & PROCEDURE [ ] PLAN	11/16	11/16	D/I	30	NG	30348.99

TITLE:

CONTINUOUS GLUCOSE MONITORING SYSTEM (CGM) PATIENT MANAGED

SUBJECT:

Equipment

KEYWORD(S): Continuous Glucose Monitoring System **(**CGM), Insulin Pump, Tubeless Insulin Pump, Computed Tomography (CT), CAT Scan, MRI

[ ] All Sharp HealthCare	AFFECTED DEPARTMENTS:	ACCREDITATION:
[ ] System Services Surgery Centers: [ ] SRS [ ] CV-OPS [ ] SCMG [ ] GPSC [ ] SHP [ ] SMH-OPP	All patient care areas, Radiology, OR, Cardiac Catheterization Lab	
Hospitals (check all that apply): [X] SCOR [X] SMH [X] SCVMC [X] SMBHWN [X] SGH [X] SMV [ ] SMC	ORIGINATOR: Diabetes Service Line	LEGAL REFERENCES:

I. PURPOSE:

To provide guidelines for the safe use of the patient's own Continuous Glucose Monitoring (CGM) device in all patient care areas (for insulin pump therapy, see policy 30090.99).

A. **Only patients with a Physician order may be allowed to continue to wear CGM.**
B. This device is indicated for detecting trends and tracking glycemic patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia.
C. **The CGM will be used to complement, not eliminate or replace Blood Glucose (BG) checks using the hospital approved blood glucometer(s) or Laboratory BG**
D. CGM systems have not been tested during MRI, CT scans, or diathermy treatment (electric instruments generating heat), and it is unknown if X-ray exposure during standard X-ray imaging studies will have an adverse effect. Nevertheless, manufacturers recommend that sensor, transmitter, and receiver should be removed prior to any procedure that involves exposure to Magnetic Fields, MRI, CT scan or diathermy treatment. The CGM receiver should not accompany the patient to such procedure locations. CGM to be covered by lead apron for X Ray, Fluoroscopy and Bone Density testing.
E. Also patients who are receiving Acetaminophen (such as Tylenol) during their hospital stay must be informed that this may cause the CGM blood glucose readings to be falsely elevated.

II. DEFINITIONS:

A. **Continuous Glucose Monitoring Systems are FDA approved** devices available by prescription. These devices provide real-time measurements of glucose levels, with glucose levels displayed at 1 to 5 minute intervals. Users can set alarms to alert them when glucose levels are too low or too high. CGM systems usually consist of a glucose sensor; a transmitter, and a small external display monitor or an insulin pump (see Policy #30090.99 for insulin pumps).
B. **Glucose Sensor**: A tiny sensor is inserted under the skin to check glucose levels in interstitial fluid. The sensor stays in place for several days to a week and then must be replaced.
C. **Transmitter** sends information about glucose levels that are wirelessly sent to a stand-alone receiver and/or an insulin pump to view glucose levels. Transmitters attach to each new Glucose Sensor upon insertion and are not disposable.
D. **Receiver** displays the patients glucose trends so they can easily see when it's high, low or within range.
E. **Integrated insulin pump and CGM system**. CGM sensor transmits blood glucose results wirelessly to the insulin pump which can take action based on the glucose and the programmable features of the insulin pump.
F. **Computerized Tomography (CT)**: An imaging technique using computerized axial tomography.

G. **Magnetic Resonance Imaging (MRI)**: An imaging technique using a magnetic field and radio waves.

H. **Diathermy treatment and Electro-Cautery**: A technique involving the production of heat in a part of the body by high-frequency electric currents, to stimulate the circulation, relieve pain, destroy unhealthy tissue, or cause bleeding vessels to clot.

I. **Example:**

A: Transmitter B: Glucose Sensor GGM System with receiver

III. TEXT:

A. Patients with a CGM, may be allowed to continue wearing and using the device upon a physician order and has been assessed by their managing physician as soon after admission as possible to verify:
   1. That the patient is competent to use the CGM (attachment A)
   2. The patient understands the items required by the Hospital to use the CGM
   3. The physician will order the CGM power plan if the patient is to continue wearing the device

B. Precautions and special items

1. Patients must review and sign the patient CGM agreement. Patients who refuse to comply with the agreement will not be allowed to use the CGM during the hospital admission
2. Patient is aware that only BG results performed by nursing staff using hospital approved POC meters and lab serum glucose will be utilized to make treatment decisions. The patient is informed that the CGM results are used to supplement Point Of Care/Lab glucose and will not be used to adjust treatment
3. The patient will provide ALL supplies required in the use of their CGM during their hospitalization
4. The patient will be required **to remove the CGM sensor, transmitter, and receiver** as well as insulin pump where applicable, during any of the procedures outlined in the CGM and Insulin Pump Safety Precautions identified in Table 1 as well as the patient agreement (see Attachment A)
5. Patients who are receiving Tylenol during their hospital stay must be informed that this may cause the CGM blood glucose readings to be falsely elevated
6. The provider, patient and RN must be aware that hypoglycemia or hyperglycemia treatment would only take place once a POC BG or lab glucose result verifies the result

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Table 1: CGM and Insulin Pump Safety Precaution Table

(√) **Denotes Should** NOT be Exposed to Magnetic Fields and Radiation	CGM Only	Insulin Pump Only*	CGM and Insulin Pump*	Guidelines
MRI	X	X	X	~Do Not Bring Pump/ Transmitter/Sensor/ Receiver into the same room where the procedure is being performed. ~Teflon/plastic infusion set can remain in. Other types of Infusion sets must be removed.
CT -Scan	X	X	X	
Electro-Cautery	X	X	X	
Diathermy Treatments	X	X	X	
Direct X-Ray	X	X	X	
Cardiac Catheterization		X	X	
Nuclear Stress Test		X	X	
Pacemaker/AICD Placement/reprogramming		X	X	
*Pump may be disconnected from tubing and placed behind protective shield.				

(√) **Denotes a lead apron** that completely covers the Sensor and Transmitter must be worn during the procedure	CGM Only	Insulin Pump Only *	CGM and Insulin Pump*	Guidelines
X-Ray - Body Fluoroscopy (Cardiac Catheterization; Nuclear Stress Test; Pacemaker/AICD Placement/reprogramming)	X			~ Teflon/plastic infusion set can remain in. Other types of Infusion sets must be removed.
Bone Density	X			
Portable X-ray	X			
*Pump may be disconnected from tubing and placed behind protective shield.				

Pump, Infusion set and Transmitter/Sensor can remain on/in	CGM Only	Insulin Pump Only	CGM and Insulin Pump	Guidelines
Colonoscopy	X	X	X	No Restrictions
EKG	X	X	X	
Laser Surgery	X	X	X	
Ultrasound	X	X	X	

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IV. PROCEDURE:	**RESPONSIBILITY**
A. The Physician (Provider) will order the CGM power plan once verification obtained that the patient is competent to use the device.	Physician
B. The nurse will provide the patient with the Patient Agreement on use of CGM in the hospital (attachment A). 1. Review the Agreement with the patient to verify understanding. 2. Obtain initials and signature of the patient upon completion of the review. 3. The patient needs to be told that failure to sign the document and to comply with the hospital policy waives any and all claims, demands, actions, or suits against the hospital relating to the use of the device. 4. The nurse who reviewed the form with the patient will sign the form. 5. Document that existing sensor is in situ, with date and time last changed. 6. Place one copy of the form in the patient record. 7. Provide the patient with a second copy of the form.	RN/ Patient
C. Provide ALL supplies for my CGM. Change my CGM site and calibrate as per the manufacturers recommendations.	Patient
D. The patient inserts the sensor, calibrates and maintains the transmitter and receiver per manufactures recommendations.	Patient
E. The Nurse will: 1. Perform all BG monitoring using hospital approved glucometer. 2. The nurse will check Insertion site every shift for redness or swelling. 3. The nurse will document and report the existence of a CGM with any patient transfer off the unit. 4. Place the “CGM” sign in the patient’s room. 5. Acknowledge the presence of a CGM or insulin Pump in the Cerner Acute Patient Intake form as soon as possible (not to exceed 24hrs).	Nurse
F. Disconnect/Remove Sensor – See picture II. B. The CGM must be removed in the event of hospital procedures as outlined in the **CGM and Insulin Pump Safety Precaution Table**. The patient will disconnect the transmitter from the sensor and place the transmitter in their bedside table or hospital safe for safe keeping. The sensor is to be discarded in the sharps container as it may contain a needle.	Patient/RN

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IV. PROCEDURE:	**RESPONSIBILITY**
G. Notify the nurse if CGM trends indicate hypo/hyperglycemia with or without symptoms of hypo/hyperglycemia so that a POC BG may be obtained promptly. 1. Hypoglycemia treatment may be initiated per patient request based on trend or following the SHC Hypoglycemia Standardized Procedure if no other order exists. 2. If BG is less than 70 mg/dL, (< 60mg/dL in obstetric patient) treat according to physician orders. If no orders exist, treat per Hypoglycemia Standardized Procedure. If the BG 70-120 mg/L (60-120 mg/dL for obstetric patient) and the patient requests treatment, provide the patient with the snack requested. Call provider if NPO. For BG > 120 mg/dL, call provider if patient requests treatment and no order is present.	G. Patient/RN

V. REFERENCES:

A. Damiano, E.R. et al. (2014) A Comparative Effectiveness Analysis of Three Continuous Glucose Monitors: The Navigator, G4 Platinum and Enlite. *Journal of Diabetes Science and Technology*, (8) 699-708.

B. Manufacturer User Guide (Dexcom G4, Dexcom Seven Plus, Medtronic 530 G, Animas Vibe Pump) subject to change as new technology emerges.

C. Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology and Metabolism*, June 30 20161945-7197

VI. CROSS REFERENCES:

A. SHC P&P #30090.99 Subcutaneous Insulin Pump Therapy
B. SHC P&P #18744.99 Radiation Safety: Diagnostic Imaging and Radiation exposure to electronic medical devices.
C. SHC P&P #18006.99 Patient-Supplied Medical Device
D. SHC P&P #30094.99 Treatment of Hypoglycemia

VII. ATTACHMENTS: (Control + Click on Attachments to access and/or print)

A. Patient Glucose Monitoring Agreement (English)
B. Patient Glucose Monitoring Agreement (Spanish)

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VIII. APPROVALS:

A. System Nursing Policy & Procedure Committee – 06/16
B. System Policy & Procedure Steering Committee – 09/16
C. System Committee for Imaging Policy & Education – 09/16
D. Pharmacy & Therapeutics **OR** Treatment & Surveillance:

SMH/ SMMC	SMBWH	SGH	SCVMC	SCOR	SMV
05/03/16	05/18/16	8/30/16	1/25/2016	6/27/16	6/21/16

IX. REPLACES: None

X. HISTORY: System #30348.99; originally dtd. 11/16
Reviewed\Revised: N/A