Prior Authorization Process for Continuous Glucose Monitoring Systems and Insulin Pumps

June 25, 2020
Objectives

- Promote understanding of the HUSKY Health program’s Prior Authorization (PA) process for continuous glucose monitoring systems and insulin pumps
- Explain documentation requirements and coverage criteria
- Reduce the administrative burden associated with the PA process
All HUSKY Health members are eligible to receive healthcare goods or services from Connecticut Medical Assistance Program (CMAP) enrolled providers

*Only CMAP enrolled providers will be reimbursed* for goods or services provided to HUSKY Health members

All ordering, prescribing, or referring practitioners must be enrolled as either an ordering/prescribing/referring (OPR) or CMAP provider

Medical necessity determinations are made on a case-by-case, person-centered assessment of members and their clinical needs

Payment is based on the member having active coverage, benefits, and policies in effect at the time of service
Definition of Medical Necessity

- All determinations are made on the basis of medical necessity and must be in compliance with the Definition of Medical Necessity, Connecticut General Statutes § 17b-259b(a)

- “Medical Necessity” (or “Medically Necessary”) means those health services required to prevent, identify, diagnose, treat, rehabilitate, or ameliorate an individual’s medical condition; including mental illness, or its effects, in order to attain or maintain the individual’s achievable health and independent functioning provided such services are:

  (1) Consistent with generally-accepted standards of medical practice that are defined as standards based on:

    (A) Credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community,
    
    (B) Recommendations of a physician-specialty society,
    
    (C) The views of physicians practicing in relevant clinical areas, and
    
    (D) Any other relevant factors;
Definition of Medical Necessity (cont.)

(2) Clinically appropriate in terms of type, frequency, timing, site, extent and duration, and considered effective for the individual’s illness, injury, or disease

(3) Not primarily for the convenience of the individual, the individual’s healthcare provider, or other healthcare providers;

(4) Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual’s illness, injury, or disease

(5) Based on an assessment of the individual and his/her medical condition

All final determinations of medical necessity must be based upon this statutory definition.
Process Changes

- Effective July 1, 2020, Community Health Network of Connecticut, Inc.® (CHNCT) will be retiring the medical policies for continuous glucose monitoring systems and insulin pumps.
- Requests for these goods will be reviewed using the Definition of Medical Necessity along with InterQual criteria.
- Requests that do not meet criteria will also be given an individual, person-centered review.
Continuous Glucose Monitoring Systems
Documentation Requirements

- PA form or online portal submission
- Prescription
- Clinical documentation
Prescription

- Per Section 17b-262-721(f) of the Regulations of Connecticut State Agencies, all medical and surgical supplies prescriptions/orders shall include the following:
  - Member’s name, address, and date of birth
  - Diagnosis for which the medical and surgical supplies are required
  - Detailed description of the medical and surgical supplies, including quantities and directions for usage, when appropriate
  - Length of need for the medical and surgical supplies prescribed
  - Prescribing practitioner’s name, address, signature, and signature date and
  - NPI number of the ordering, prescribing, referring practitioner
Flash Monitors
Flash Monitors

- Coding changes
  - K0554 – Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitoring (CGM) system
  - K0553 – Supply allowance for therapeutic continuous glucose monitor, including all supplies and accessories, 1 month supply = 1 unit

The intermittent or “flash” CGM device, which differs from the traditional CGM in that it does not have alarms, does not require calibration with self-monitoring of blood glucose (SMBG), and does not communicate continuously, although it does record the glucose level and this information is stored and can be obtained on demand.
Flash Monitor Criteria

- Diagnosed with diabetes mellitus requiring insulin therapy
- Blood glucose testing $\geq$ 4 times per day
- Insulin injections $\geq$ 3 times per day or use of insulin pump
- Frequent adjustments to treatment regimen necessary based on glucose testing results
- Documented compliance to physician-directed comprehensive diabetes management program
Flash Monitor Criteria (cont.)

- Documentation supports
  - Training and comprehension in use of CGM device
  - Education regarding importance of daily use
  - Patient or caregiver is willing and motivated
  - Substance use disorder excluded or treated
  - Behavioral health disorder excluded or treated

- Glycemic monitoring necessary due to at least 1 clinical indication
  - Hyperglycemia following meals
  - Wide glycemic swings
  - Diabetic ketoacidosis
  - HbA1c level $\geq 7\%$ or outside individualized targets
Therapeutic CGM
Therapeutic CGM

- Coding changes
  - K0554 – Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitoring (CGM) system
  - K0553 – Supply allowance for therapeutic continuous glucose monitor, including all supplies and accessories, 1 month supply = 1 unit

A therapeutic CGM is defined as a CGM used as a replacement for fingerstick blood glucose testing for diabetes treatment decisions (i.e., non-adjunctive use). CGM devices can be “non-adjunctive” or “therapeutic,” where treatment decisions do not require SMBG verification, but calibration is required, typically every 12 hours.
Therapeutic CGM Criteria

- Diagnosed with diabetes mellitus requiring insulin therapy
- Blood glucose testing ≥ 4 times per day
- Insulin injections ≥ 3 times per day or use of insulin pump
- Frequent adjustments to treatment regimen necessary based on glucose testing results
- Documented compliance to physician-directed comprehensive diabetes management program
Therapeutic CGM Criteria (cont.)

- Documentation supports
  - Training and comprehension in use of CGM device
  - Education regarding importance of daily use
  - Patient or caregiver is willing and motivated
  - Substance use disorder excluded or treated
  - Behavioral health disorder excluded or treated

- Glycemic monitoring necessary due to at least 1 clinical indication
  - Unexplained, nocturnal, or severe hypoglycemia
  - Hypoglycemia unawareness
  - Hyperglycemia following meals
  - Wide glycemic swings
  - Diabetic ketoacidosis
  - HbA1c level $\geq$ 7% or outside individualized targets
Non-therapeutic CGM
Non-therapeutic CGM

Coding

- A9278 – Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
  - Expected life 3 to 5 years
- A9277 – Transmitter, external, for use with interstitial continuous glucose monitoring system
- A9276 – Sensor, invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system

Non-therapeutic CGM are devices used as an adjunct to blood glucose monitor testing. Primary therapeutic decisions regarding diabetes treatment must be made with a standard home blood glucose monitor, not the CGM.
Non-therapeutic CGM Criteria

- Diagnosed with diabetes mellitus requiring insulin therapy
- Blood glucose testing $\geq$ 4 times per day
- Insulin injections $\geq$ 3 times per day or use of insulin pump
- Frequent adjustments to treatment regimen necessary based on glucose testing results
- Documented compliance to physician-directed comprehensive diabetes management program
Non-therapeutic CGM Criteria (cont.)

- Documentation supports
  - Training and comprehension in use of CGM device
  - Education regarding importance of daily use
  - Patient or caregiver is willing and motivated
  - Substance use disorder excluded or treated
  - Behavioral health disorder excluded or treated

- Glycemic monitoring necessary due to at least 1 clinical indication
  - Unexplained, nocturnal, or severe hypoglycemia
  - Hypoglycemia unawareness
  - Hyperglycemia following meals
  - Wide glycemic swings
  - Diabetic ketoacidosis
  - HbA1c level $\geq 7\%$ or outside individualized targets
Sensor Augmented Therapy

CGM devices can be used as stand-alone devices or in conjunction with compatible insulin pumps. When CGM is used together with an insulin pump, it may be referred to as a sensor augmented pump therapy. When the monitor transmits information to the pump software to adjust or suspend insulin dosing, the system is referred to as an integrated “closed loop” insulin pump system or “artificial pancreas” system.
Insulin Pumps
Covered Diagnosis

- Diabetes mellitus type 1
- Diabetes mellitus type 2
- Gestational diabetes treated with insulin, without pre-existing type 1 or 2 diabetes
Covered Pumps

- Insulin pump or insulin delivery system
- Artificial pancreas sensor augmented insulin pump system with low glucose suspend feature
- Artificial pancreas hybrid closed loop system
Current Coding

- Insulin pump – all types
  - E0784
- External, ambulatory insulin delivery system, disposable
  - A9274
- Integrated CGM
  - K0553 for therapeutic CGM
  - A9277, A9276 for non-therapeutic
  - Separate receivers would not be needed as the insulin pump acts as the receiver
Insulin Pump Criteria

- Glucose testing $\geq$ 4 times per day for $\geq$ 8 weeks
- Completed a diabetes management program
- Insulin injections $\geq$ 3 times per day and self-adjusted dose changes $\geq$ 6 months
- Unexplained, nocturnal, or severe hypoglycemia
- Hypoglycemia unawareness
- Dawn phenomenon blood glucose $> 200\text{mg/dL}$
Insulin Pump Criteria (cont.)

- Wide and unpredictable (erratic) swings in blood glucose levels
- Glycemic targets within individualized range, but lifestyle requires increased flexibility of insulin pump use
- HbA1c level ≥ 7% or outside individualized targets
- Assessment by diabetes care team documents
  - Patient or caregiver motivated to assume responsibility for self-care and insulin management
  - Patient or caregiver demonstrates knowledge of importance of nutrition including carbohydrate counting and meal planning
Additional Criteria

- Artificial pancreas sensor augmented insulin pump system with low glucose suspend feature
  - Patient or caregiver motivated to assume responsibility for self-care and insulin management
  - Patient or caregiver demonstrates knowledge of importance of nutrition, including carbohydrate
  - Supplemental testing with a self-monitoring blood glucose device planned
  - Cognitive status appropriate to manage device technology and for response to device and alarms
Additional Criteria (cont.)

- Artificial pancreas hybrid closed loop system
  - Patient or caregiver motivated to assume responsibility for self-care and insulin management
  - Patient or caregiver demonstrates knowledge of importance of nutrition, including carbohydrate
  - Supplemental testing with a self-monitoring blood glucose device planned
  - Cognitive status appropriate to manage device technology and for response to device and alarms
  - Total daily insulin dose is $\geq 8$ units
Insulin Pump Considerations

- Refer to current practice guidelines and manufacturer/FDA recommendations for indications of use
  - Primary diagnosis
  - Age
  - Pregnancy status
Review Timeframe
Review Timeframe

- Once a request is submitted, a pending authorization number is generated.
- If more information is needed, the clinical reviewer will contact the provider via fax, phone, and/or email; if additional information is required, the provider is given additional time to submit the requested information.
- All requests for Durable Medical Equipment (DME) are reviewed within 14 calendar days from the date of receipt.
- A decision must be made by the 20th business day from the date of receipt.
Request Approvals

- Approval letters are generated after the request approval has been given
- The approval letter is mailed to the member and faxed to the DME provider
Request Denials

- Denial letters are mailed to the member and faxed to the ordering physician and DME provider within three business days of the determination.
Questions/Comments