MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 06/05/18
LAST REVIEW DATE:
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CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Description:

Glucose monitoring of the interstitial fluid is a technique of automatically measuring glucose levels throughout the day to provide trends in glucose measurements, in contrast to traditional isolated blood glucose levels. Monitors may be integrated (combined) with external insulin infusion pumps or non-integrated.

According to the FDA labeling, monitors are not intended to be an alternative to traditional self-monitoring of blood glucose levels but rather provide adjunct monitoring, supplying additional information on glucose trends that are not available from self-monitoring. In addition, it is important to note that devices may be used intermittently, e.g., time periods of 72 hours, or on a long-term basis.

Information on trends in glucose levels may benefit individuals with type I diabetes that have inadequate control, including episodes of hypoglycemia, despite compliance with best practices.

FDA Approved Continuous Glucose Monitors Devices Include:
- Continuous Glucose Recorder Monitoring System (CGMS®) (Medtronic, MiniMed)
- Dexcom® STS CGM
- Dexcom™ STS-7™ CGMS
- DexCom® G4 Platinum CGMS
- DexCom® G5 Mobile CGMS
- FreeStyle Navigator® CGMS (Abbott)
- Guardian® RT (Real-Time) CGMS (Medtronic, MiniMed)
- Freestyle Libre® Pro Flash Glucose Monitoring System

FDA Approved Combined Continuous Glucose Monitors with External Insulin Pump Devices Include:
- Paradigm® REAL-Time System (second generation called Paradigm Revel System) (Medtronic, MiniMed) for age seven years and older.

Non-FDA Approved Devices Include:
- Eversense™ Continuous Glucose Monitoring (CGM) System: has been investigated to continually measure interstitial fluid glucose levels in adults with diabetes. System includes transmitter with alert feature and a sensor that is subcutaneously implanted for up to 90 days.

Definitions:

Best Practices:
- 4 or more fingersticks per day and use of an insulin pump
- During pregnancy, 3 or more insulin injections per day for individuals not on an insulin pump prior to the pregnancy
- Prior use of an intermittent (72-hour) glucose monitor for individuals considering use of a continuous glucose monitor

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Criteria:

For artificial pancreas systems, see BCBSAZ Medical Coverage Guideline #O934, *"Artificial Pancreas Device Systems"*.

Continuous Glucose Monitoring:

- Continuation of coverage for ongoing supplies for members already approved for continuous glucose monitoring is considered ***medically necessary***.

- Continuous monitoring of glucose levels in the interstitial fluid alone or in combination with an external insulin infusion pump in an individual 7 years of age or older is considered ***medically necessary*** with documentation of **ANY** of the following despite use of best practices (see Description section):

  1. Individual with type I diabetes with documentation of **ALL** of the following:

     - Demonstrated understanding of the technology and motivation to use device consistently and correctly
     - Expected to be adherent to comprehensive diabetes treatment plan supervised by a qualified provider (e.g., provider is board certified in endocrinology and/or provider with a focus on the practice of diabetes care)
     - Capable of using the device and recognizing alerts and alarms

  2. Individual with type I diabetes who has recurrent, unexplained, severe hypoglycemia (blood glucose levels less than 50mg/dl) for whom the hypoglycemia or impaired awareness of hypoglycemia puts the individual or others at risk
  3. Pregnant individual with type I diabetes that is poorly controlled with documentation of **ANY** of the following:

     - Diabetic ketoacidosis, recurrent
     - Hypoglycemic unawareness
     - Suspected postprandial hyperglycemia
     - Unexplained hypoglycemic episodes

- Continuous monitoring of glucose levels in the interstitial fluid alone or in combination with an external insulin infusion pump for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Criteria: (cont.)

Continuous Glucose Monitoring: (cont.)

- Arizona statutory coverage mandates do not require coverage of continuous glucose monitoring devices unless ***medically necessary***.

- Although rental of the device is ***not eligible for coverage***, the professional services for consultation and review of data are ***eligible for coverage*** as evaluation and management (E/M) services with appropriate documentation.

Intermittent Glucose Monitoring (up to 72 hours):

If medical necessity criteria are met, any FDA-approved CGM device is eligible for coverage (see Description section).

- Intermittent monitoring of glucose levels in the interstitial fluid is considered ***medically necessary*** for an individual with type I diabetes to determine baseline insulin levels prior to insulin pump initiation.

- Intermittent monitoring of glucose levels in the interstitial fluid is considered ***medically necessary*** for an individual with type I diabetes that is poorly controlled despite use of best practices (see Description section) with documentation of **ANY** of the following:

    1. Diabetic ketoacidosis, recurrent
    2. Hypoglycemic unawareness
    3. Suspected postprandial hyperglycemia
    4. Unexplained hypoglycemic episodes

- Intermittent monitoring of glucose levels in the interstitial fluid for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

    1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
    2. Insufficient evidence to support improvement of the net health outcome, and
    3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Resources:

Literature reviewed through 06/05/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 1.01.20 BCBS Association Medical Policy Reference Manual. Continuous or Intermittent Monitoring of Glucose in the Interstitial Fluid. Re-issue date 03/08/2018, issue date 08/18/2000.

2. Arizona Revised Statutes. Annotated sections 20-828, 20-1057, and 20-2325.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh íłínígóó. Ata' halne'ígíí kojį' bich'į' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799
.[تماس حاصل نمایید.

Assyrian:

[illegible] Blue Cross Blue Shield of Arizona، [illegible]
[illegible] 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799