BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 02/24/15**
SECTION: Durable Medical Equipment (DME)	**LAST REVIEW DATE: 01/22/19**
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	ARCHIVE DATE:

ARTIFICIAL PANCREAS DEVICE SYSTEMS

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.

ARTIFICIAL PANCREAS DEVICE SYSTEMS (cont.)

Description:

Artificial Pancreas or Artificial Pancreas Device Systems (APDS):
Artificial pancreas device systems are medical devices that link a glucose monitor to an insulin infusion pump, in which the pump automatically takes action (using a control algorithm) based on the glucose monitor reading. The goal of the APDS is to automatically monitor glucose levels and adjust insulin levels. These devices are proposed to improve glycemic control in individuals with insulin-dependent diabetes, in particular control of nocturnal hypoglycemia. These systems are also referred to as closed-loop systems or autonomous systems for glucose control.

Threshold Suspend Device System:
Also referred to as low glucose suspend (LGS) systems. With LGS or threshold suspend device systems, the delivery of insulin is suspended for a set time when 2 glucose levels are below a specified low level indicating hypoglycemia.

Control-to-Range System:
With these systems, the individual sets his or her own insulin dosing within a specified range, but the artificial pancreas device system takes over if glucose levels reach outside that range (higher or lower). Individuals using this type of system still need to check blood glucose levels and administer insulin as needed.

Control-to-Target System:
With this type of device, the system aims to maintain glucose levels near a target level, such as 100 mg/dL. Control-to-target systems are automated and do not require participation of the user except for calibration of the continuous glucose monitoring system. Several device subtypes are being developed i.e., those that deliver insulin-only, bi-hormonal systems and hybrid systems.

ARTIFICIAL PANCREAS DEVICE SYSTEMS (cont.)

Description: (cont.)

FDA Approved Artificial Pancreas Device Systems:

MiniMed® 530G System:
Is classified as a LGS or threshold suspend device system which integrates an insulin pump and glucose meter. FDA clearance was granted in 2013. The threshold suspend tool temporarily suspends insulin delivery when the sensor glucose level is equal to or lower than a pre-set threshold within the 60 mg/dL to 90 mg/dL range. When the glucose value reaches this threshold, an alarm sounds. If individuals respond to the alarm, they can choose to continue or cancel the insulin suspend feature. If individuals fail to respond to the alarm, the pump automatically suspends action for 2 hours, and then insulin therapy resumes.

The system is approved for use in individuals 16 years and older.

MiniMed® 630G System with SmartGuard™:
LGS or threshold suspend device system that is similar to the 530G but offers updates to the system components including waterproofing.

The system is approved for use in individuals 16 years and older.

MimiMed® 670G System:
Is classified as a hybrid closed-loop insulin delivery system approved by FDA in 2016. It consists of an insulin pump, a glucose meter and a transmitter, linked by a proprietary algorithm, the SmartGuard HCL.

The system includes an LGS feature that suspends insulin delivery when glucose levels get low and has an optional alarm. Additionally, the system involves semi-automatic insulin level adjustment to preset targets. Basal insulin levels are automatically adjusted but the individual needs to administer pre-meal insulin boluses.

The system is approved for use in individuals 14 years and older with type 1 diabetes. It is contraindicated in children under age 7 and in individuals who require less than a total daily insulin dose of 8 units.

ARTIFICIAL PANCREAS DEVICE SYSTEMS (cont.)

Criteria:

For continuous or intermittent glucose monitoring, see BCBSAZ Medical Coverage Guideline #O388, *"Continuous or Intermittent Glucose Monitoring in Interstitial Fluid"*.

If medical necessity criteria are met, any FDA-approved artificial pancreas device system with a low glucose suspend feature is eligible for coverage.

- Artificial pancreas device system use with a low glucose suspend feature is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Age 16 and older
  2. Type 1 diabetes
  3. Glycated hemoglobin level between 5.8% and 10.0%
  4. Used insulin pump therapy for more than 6 months
  5. At least 2 documented nocturnal hypoglycemic events in a 2 week period

- Artificial pancreas device system use 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

- Use of hybrid closed loop insulin delivery system as an artificial pancreas device system 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

ARTIFICIAL PANCREAS DEVICE SYSTEMS (cont.)

Resources:

Literature reviewed through 02/20/18. 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. 1.01.30 BCBS Association Medical Policy Reference Manual. Artificial Pancreas Device Systems. Re-issue date 12/14/2017, issue date 01/15/2015.

ARTIFICIAL PANCREAS DEVICE SYSTEMS (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 hólǫ 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.

ARTIFICIAL PANCREAS DEVICE SYSTEMS (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