Medical Coverage Policy | Artificial Pancreas Device System

EFFECTIVE DATE: 07|01|2014
POLICY LAST UPDATED: 08|05|2014

OVERVIEW
Tight glucose control in patients with diabetes has been associated with improved outcomes. Several devices are available to measure glucose levels automatically and frequently (eg, every 5-10 minutes). An Artificial Pancreas Device System (APDS) is an innovative device that automatically monitors blood glucose and provides appropriate insulin doses in people with diabetes who use insulin.

PRIOR AUTHORIZATION
Not applicable.

POLICY STATEMENT
BlueCHiP for Medicare and Commercial
Artificial Pancreas Device Systems are considered **not medically necessary** because there is insufficient medical literature to support the efficacy of this treatment.

MEDICAL CRITERIA
Not applicable.

BACKGROUND
An artificial pancreas device system (APDS) is a series of devices, eg, a continuous glucose monitor (CGM), blood glucose device and an insulin pump, plus a computer algorithm that communicates with all of the devices. The goal of the APDS is to automatically monitor glucose levels and adjust insulin levels. These systems are also called closed-loop systems or autonomous systems for glucose control. One technology associated with artificial pancreas development is a "low glucose suspend (LGS)" feature included with an insulin pump. The LGS feature is designed to suspend insulin delivery when plasma glucose levels fall below a prespecified threshold.

The Minimed 530G System (Medtronic) was the first device categorized by the FDA as an artificial pancreas device system and was cleared for marketing by FDA in September 2013. The system integrates a CGM and insulin pump and includes a low glucose suspend (LGS) feature that can automatically temporarily suspend insulin delivery when glucose levels fall below a prespecified level. The device is approved only for use in patients 16 years and older.

The evidence is insufficient to permit conclusion on the impact of the artificial pancreas device system, with low glucose suspend feature, on health outcomes. A single RCT using an FDA-approved device has reported the results of its use in a home setting. Due to the limited evidence and lack of approved devices, use of artificial pancreas systems is considered not medically necessary.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

CODING
The following codes are **not medically necessary for BlueCHiP for Medicare and Commercial:**

S1034, S1035, S1036, S1037

RELATED POLICIES
Glucose Monitoring Systems

PUBLISHED
Provider Update Oct 2014

REFERENCES

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3. Melbourne SVH. The Performance of an Artificial Pancreas at Home in People With Type 1 Diabetes (NCT02040571). Available online at: www.clinicaltrials.gov. Last accessed February, 2014.

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6. American Diabetes A. Standards of medical care in diabetes--2013. Diabetes Care 2013; 36 Suppl 1:S11-66.