BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 1.01.30 Artificial Pancreas Device Systems

Effective Policy Date: October 1, 2023

Original Policy Date: March 2015

Related Policies:

7.03.02 - Allogeneic Pancreas Transplant
7.03.12 - Islet Transplantation

Artificial Pancreas Device Systems

Description

Description

Automated insulin delivery systems, also known as artificial pancreas device systems, link a glucose monitor to an insulin infusion pump that automatically takes action (e.g., suspends or adjusts insulin infusion) based on the glucose monitor reading. These devices are proposed to improve glycemic control in patients with insulin-dependent diabetes, in particular, reduction of nocturnal hypoglycemia.

OBJECTIVE

The objective of this evidence review is to determine whether artificial pancreas device systems improve the net health outcome in individuals with type 1 diabetes compared with standard glucose monitoring, either continuous glucose monitoring or self-monitoring of blood glucose, plus an insulin pump or multiple insulin injection therapy.

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POLICY STATEMENT

Use of a U.S. Food and Drug Administration (FDA) cleared or approved automated insulin delivery system (artificial pancreas device system) with a low-glucose suspend feature may be considered **medically necessary** in individuals with type 1 diabetes who meet all of the following criteria:

Age 6 years and older AND

- Glycated hemoglobin level between 5.8% and 10.0%;
- Used insulin pump therapy for more than 6 months;
- At least 2 documented nocturnal hypoglycemic events in a 2-week period.

Use of a FDA cleared or approved automated insulin delivery system (artificial pancreas device system) designated as a hybrid closed-loop insulin delivery system (with low glucose suspend and suspend before low features) may be considered **medically necessary** in individuals with type 1 diabetes who meet all of the following criteria:

Over age 6 years AND

- Glycated hemoglobin level between 5.8% and 10.0%;
- Used insulin pump therapy for more than 6 months;
- At least 2 documented nocturnal hypoglycemic events in a 2-week period.

OR

- Age 2 to 6 years AND
    - Clinical diagnosis of type 1 diabetes for 3 months or more;
    - Used insulin pump therapy for more than 3 months;
    - Glycated hemoglobin level <10.0%;
    - Minimum daily insulin requirement (Total Daily Dose) of greater than or equal to 8 units.

Use of a FDA cleared or approved automated insulin delivery system (artificial pancreas device system) designated as a closed-loop insulin delivery system may be considered **medically necessary** in individuals with type 1 diabetes who meet all of the following criteria:

- Age 6 years and older AND
    - Clinical diagnosis of type 1 diabetes for 12 months or more;
    - Using insulin for at least 12 months;
    - Diabetes managed using the same regimen (either pump or multiple daily injections, with or without continuous glucose monitoring) for 3 months or longer.

Use of an automated insulin delivery system (artificial pancreas device system) is **investigational** for individuals who do not meet the above criteria.

Use of an automated insulin delivery system (artificial pancreas device system) not cleared or approved by the FDA is **investigational.**

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

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FDA REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) describes the basic design of an artificial pancreas device system as a continuous glucose monitoring linked to an insulin pump with the capability to automatically stop, reduce, or increase insulin infusion based on specified thresholds of measured interstitial glucose.[5,]

The artificial pancreas device system components are designed to communicate with each other to automate the process of maintaining blood glucose concentrations at or near a specified range or target and to minimize the incidence and severity of hypoglycemic and hyperglycemic events. An artificial pancreas device system control algorithm is embedded in software in an external processor or controller that receives information from the continuous glucose monitoring and performs a series of mathematical calculations. Based on these calculations, the controller sends dosing instructions to the infusion pump.

Different artificial pancreas device system types are currently available for clinical use. Sensor augmented pump therapy with low glucose suspend (suspend on low) may reduce the likelihood or severity of a hypoglycemic event by suspending insulin delivery temporarily when the sensor value reaches (reactive) a predetermined lower threshold of measured interstitial glucose. Low glucose suspension automatically suspends basal insulin delivery for up to 2 hours in response to sensor-detected hypoglycemia.

A sensor augmented pump therapy with predictive low glucose management (suspend before low) suspends basal insulin infusion with the prediction of hypoglycemia. Basal insulin infusion is suspended when sensor glucose is at or within 70 mg/dL above the patient-set low limit and is predicted to be 20 mg/dL above this low limit in 30 minutes. In the absence of a patient response, the insulin infusion resumes after a maximum suspend period of 2 hours. In certain circumstances, auto-resumption parameters may be used.

When a sensor value is above or predicted to remain above the threshold, the infusion pump will not take any action based on continuous glucose monitoring readings. Patients using this system still need to monitor their blood glucose concentration, set appropriate basal rates for their insulin pump, and give premeal bolus insulin to control their glucose levels.

A control-to-range system reduces the likelihood or severity of a hypoglycemic or hyperglycemic event by adjusting insulin dosing only if a person's glucose levels reach or approach predetermined higher and lower thresholds. When a patient's glucose concentration is within the specified range, the infusion pump will not take any action based upon continuous glucose monitoring readings. Patients using this system still need to monitor their blood glucose concentration, set appropriate basal rates for their insulin pump, and give premeal bolus insulin to control their glucose levels.

A control-to-target system sets target glucose levels and tries to maintain these levels at all times. This system is fully automated and requires no interaction from the user (except for calibration of the continuous glucose monitoring). There are 2 subtypes of control-to-target systems: insulin-only and bihormonal (eg, glucagon). There are no systems administering glucagon marketed in the United States.

A hybrid closed-loop system also uses automated insulin delivery with continuous basal insulin delivery adjustments. However, at mealtime, the patient enters the number of carbohydrates they are eating in order for the insulin pump to determine the bolus meal dose of insulin. A hybrid system option with the patient administration of a premeal or partial premeal insulin bolus can be used in either control-to-range or control-to-target systems.

An artificial pancreas device system may also be referred to as a "closed-loop” system. A closed-loop system has automated insulin delivery and continuous glucose sensing and insulin delivery without patient intervention. The systems utilize a control algorithm that autonomously and continually increases and decreases the subcutaneous insulin delivery based on real-time sensor glucose levels.

These systems are regulated by the FDA as class III device systems.

Table 1 summarizes the FDA cleared or approved automated insulin delivery systems.

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Table 1. U.S. Food and Drug Administration-Approved Automated Insulin Delivery Systems (Artificial Pancreas Device Systems)

Device	Age Indication	Manufacturer	Date Approved	PMA No./Device Code
MiniMed 530G System[a](open-loop, LGS)	≥16 y	Medtronic	Jul 2013	P120010/OZO
MiniMed 630G System with SmartGuard™[b](open-loop, LGS)	≥16 y ≥14 y	Medtronic	Aug 2016 Jun 2017	P150001/OZO P150001/S008
MiniMed 670G System[c] (HCL, LGS or PLGM)	≥14 y ≥7 to 13 y	Medtronic	Sep 2016 Jul 2018	P160017/OZP P160017/S031
MiniMed 770G System[d] (HCL)[6,]	≥2 y	Medtronic	Aug 2020	P160017/S076
MiniMed 780G System[e] (HCL)[7,]	>7 y	Medtronic	May 2023	P160017/S091
t:slim X2 Insulin Pump with Basal-IQ Technology (LGS)[8,]	>6 y	Tandem	Jun 2018	P180008/OZO, PQF
t:slim X2 Insulin Pump with Control-IQ Technology (HCL)	>6 y	Tandem	Dec 2019	DEN180058/QFG
Omnipod 5 (HCL)	>6 y	Insulet	Jan 2022	K203768 K203772
iLet Bionic Pancreas (CL)[9,]	>6 y	Beta Bionics	May 2023	K220916 K223846

CL: closed-loop; HCL: hybrid closed-loop; LGS: low glucose suspend; OZO: Artificial Pancreas Device System, threshold suspend; OZP: Automated Insulin Dosing Device System, Single Hormonal Control; PMA: premarket approval; PLGM: predictive low glucose management.

[a]MiniMed 530G System consists of the following devices that can be used in combination or individually: MiniMed 530G Insulin Pump, Enlite™ Sensor, Enlite™Serter, the MiniLink Real-Time System,
the Bayer Contour NextLink glucose meter, CareLink Professional Therapy Management Software for Diabetes, and CareLink Personal Therapy Management Software for Diabetes (at time of approval).

[b]MiniMed 630G System with SmartGuard™ consists of the following devices: MiniMed 630G Insulin Pump, Enlite Sensor, One-Press Serter, Guardian Link Transmitter System, CareLink USB, Bayer"s CONTOUR NEXT LINK 2.4 Wireless Meter, and Bayer"s CONTOUR NEXT Test Strips (at time of approval).

[c]MiniMed 670G System consists of the following devices: MiniMed 670G Pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-Press Serter, and the Contour NEXT Link 2.4 Glucose Meter (at time of approval).

[d]MiniMed 770G System consists of the following devices: MiniMed 770G Insulin Pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-Press Serter, the Accu-Chek Guide™ Link blood glucose meter, and the Accu-Chek Guide™ Test Strips.

[e]MiniMed 780G System consists of the following devices: MiniMed 780G Insulin Pump, the Guardian 4 Transmitter, the Guardian 4 Sensor (3), One-Press Serter, the Accu-Chek Guide™ Link blood glucose meter, and the Accu-Chek Guide™ Test Strips.

The MiniMed 530G System includes a threshold suspend or low glucose suspend feature.[10,] The threshold suspend tool temporarily suspends insulin delivery when the sensor glucose level is at or below a preset threshold within the 60- to 90-mg/dL range. When the glucose value reaches this threshold, an alarm sounds. If patients respond to the alarm, they can choose to continue or cancel the insulin suspend feature. If patients fail to respond, the pump automatically suspends action for 2 hours, and then insulin therapy resumes.

The MiniMed 630G System with SmartGuard™, which is similar to the 530G, includes updates to the system components including waterproofing.[11,] The threshold suspend feature can be programmed to temporarily suspend delivery of insulin for up to 2 hours when the sensor glucose value falls below a predefined threshold value. The MiniMed 630G System with SmartGuard™ is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on the values provided by the MiniMed 630G system. The device is not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond to the SmartGuard™ Suspend on Low alarm to take measures to prevent or treat hypoglycemia themselves.

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The MiniMed 670G System is a hybrid closed-loop insulin delivery system consisting of an insulin pump, a glucose meter, and a transmitter, linked by a proprietary algorithm and the SmartGuard Hybrid closed-loop.[12,] The system includes a low glucose suspend feature that suspends insulin delivery; this feature either suspends delivery on low-glucose levels or suspends delivery before low-glucose levels, and has an optional alarm (manual mode). Additionally, the system allows semiautomatic basal insulin-level adjustment (decrease or increase) to preset targets (automatic mode). As a hybrid system , basal insulin levels are automatically adjusted, but the patient needs to administer premeal insulin boluses. The continuous glucose monitoring component of the MiniMed 670G System is not intended to be used directly for making manual insulin therapy adjustments; rather it is to provide an indication of when a glucose measurement should be taken. The MiniMed 670G System was originally approved for marketing in the United States on September 28, 2016 (P160017), and received approval for marketing with a pediatric indication (ages 7 to 13 years) on June 21, 2018 (P160017/S031).

The MiniMed 770G System is an iteration of the MiniMed 670G System. In July 2020, the device was approved for use in children ages 2 to 6 years. In addition to the clinical studies that established the safety and effectiveness of the MiniMed 670G System in users ages 7 years and older, the sponsor performed clinical studies of the 670G System in pediatric subjects ages 2 to 6 years. FDA concluded that these studies establish a reasonable assurance of the safety and effectiveness of the MiniMed 770G System because the underlying therapy in the 670G system, and the associated Guardian Sensor (3), are identical to that of the 770G System.[6,]

On June 21, 2018, the FDA approved the t:slim X2 Insulin Pump with Basal-IQ Technology (PMA P180008) for individuals who are 6 years of age and older.[13,] The System consists of the t:slim X2 Insulin Pump paired with the Dexcom G5 Mobile Continuous Glucose Monitoring, as well as the Basal-IQ Technology. The t:slim X2 Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 Insulin Pump can be used solely for continuous insulin delivery and as part of the System as the receiver for a therapeutic continuous glucose monitoring. The t:slim X2 Insulin Pump running the Basal-IQ Technology can be used to suspend insulin delivery based on continuous glucose monitoring sensor readings.

In December 2019, FDA approved the t:slim X2 Insulin Pump with Control-IQ Technology through the De Novo process.[14,] The device uses the same pump hardware as the insulin pump component of the systems approved in t:slim X2 Insulin Pump with Basal-IQ Technology (P180008) and P140015. A custom disposable cartridge is motor-driven to deliver patient programmed basal rates and boluses through an infusion set into subcutaneous tissue.

In 2022, FDA approved the Omnipod 5 ACE Pump for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Omnipod 5 ACE Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

In May 2023, FDA approved the first closed-loop system through the 510(k) premarket clearance pathway.[9,]

RATIONALE

Summary of Evidence

For individuals who have type 1 diabetes who receive an artificial pancreas device system with a low-glucose suspend feature, the evidence includes 3 randomized controlled trials (RCTs) conducted in home settings. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. Primary eligibility criteria of the key RCT, the Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial, were ages 16-to-70 years old, type 1 diabetes, glycated hemoglobin levels between 5.8% and 10.0%, and at least 2 nocturnal hypoglycemic events (≤65 mg/dL) lasting more than 20 minutes during a 2-week run-in phase. Both trials required at least 6 months of insulin pump use. Both RCTs reported significantly less hypoglycemia in the treatment group than in the control group. In both trials, primary outcomes were favorable for the group using an artificial pancreas system; however, findings from 1 trial were limited by nonstandard reporting of hypoglycemic episodes, and findings from the other trial were no longer statistically significant when 2 outliers (children) were excluded from analysis. The RCT limited to adults showed an improvement in the primary outcome (area under the curve for nocturnal hypoglycemic events). The area under the curve is not used for assessment in clinical practice but the current technology does allow user and provider review of similar trend data with continuous glucose monitoring. Results from the ASPIRE study suggested that there were increased risks of hyperglycemia and potential diabetic ketoacidosis in subjects using the threshold suspend feature. This finding may be related to whether or not actions are taken by the user to assess glycemic status, the etiology of the low glucose reading (activity, diet or medication), or to resume insulin infusion. Both retrospective and prospective observational studies have reported reductions in rates and severity of hypoglycemic episodes in automated insulin delivery system users. The evidence suggests that the magnitude of reduction for hypoglycemic events in the type 1 diabetes population is likely to be clinically significant. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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For individuals who have type 1 diabetes who receive an artificial pancreas device system with a hybrid closed-loop insulin delivery system, the evidence includes multicenter pivotal trials using devices cleared by the U.S. Food and Drug Administration, supplemental data and analysis for expanded indications, and more recent studies focused on children and adolescents. Three crossover RCTs using a similar first-generation device studied and approved outside the United States have been reported. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. Of these 3 crossover RCTs 2 found significantly better outcomes (ie, time spent in nocturnal hypoglycemia and time spent in preferred glycemic range) with the device than with standard care. The third study r had mixed findings (significant difference in time spent in nocturnal hypoglycemia and no significant difference in time spent in preferred glycemic range). Additional evidence from device performance studies and clinical studies all demonstrate reductions in time spent in various levels of hypoglycemia, improved time in range (70-180 mg/ dL), rare diabetic ketoacidosis, and few device-related adverse events. The evidence suggests that the magnitude of reduction for hypoglycemic events in the type 1 diabetes population is likely to be clinically significant. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have type 1 diabetes who receive an artificial pancreas device system with a closed-loop insulin delivery system, the evidence includes a 13-week multicenter RCT of the iLet Bionic Pancreas System compared to usual care in 326 individuals ages 6 to 79 years with type 1 diabetes. Comparator group participants continued their pre-study subcutaneous insulin delivery (either multiple daily injections, an insulin pump without automation of insulin delivery, an insulin pump with predictive low glucose suspend feature, or an insulin pump as part of an HCL system) plus real-time continuous glucose monitoring (CGM).The glycated hemoglobin level decreased from 7.9% to 7.3% in the closed-loop insulin delivery system group and did not change (7.7% at both time points) in the standard-care group (mean adjusted difference at 13 weeks, −0.5%; 95%CI −0.6 to −0.3; p <0.001). The rate of severe hypoglycemia was 17.7 events per 100 participant-years in the closed-loop insulin delivery system group and 10.8 events per 100 participant-years in the standard-care group (p = 0.39). No episodes of diabetic ketoacidosis occurred in either group. The trial's results for the subgroups of adults (ages 18 and older) and youth (ages 6 to 17 years) have additionally been reported and were similar to the main results for the full cohort. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Clinical Endocrinologists et al

In 2021, the American Association of Clinical Endocrinologists published a clinical practice guideline for the use of advanced technology in the management of individuals with diabetes.[37,] The guideline included the following statements:

"Low-glucose suspend (LGS) is strongly recommended for all persons with T1D to reduce the severity and duration of hypoglycemia, whereas predictive low glucose suspend (PLGS) is strongly recommended for all persons with T1D to mitigate hypoglycemia. Both systems do not lead to a rise in mean glucose, and lead to increased confidence and trust in the technology, more flexibility around mealtimes, and reduced diabetes distress for both persons with diabetes and caregivers. Therefore, anyone with frequent hypoglycemia, impaired hypoglycemia awareness, and those who fear hypoglycemia leading to permissive hyperglycemia should be considered for this method of insulin delivery."
Grade A; High Strength of Evidence

"AID [Automated insulin delivery] systems are strongly recommended for all persons with T1D, since their use has been shown to increase TIR, especially in the overnight period, without causing an increased risk of hypoglycemia. Given the improvement in TIR and the reduction in hyperglycemia with AID, this method of insulin delivery is preferred above other modalities. For persons with diabetes with suboptimal glycemia, significant glycemic variability, impaired hypoglycemia awareness, or who allow for permissive hyperglycemia due to the fear of hypoglycemia, such AID systems should be considered."
Grade A; High Strength of Evidence

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American Diabetes Association

The American Diabetes Association has released multiple publications on controlling type 1 diabetes (Table 2).

Table 2. American Diabetes Association Recommendations on Controlling Type 1 Diabetes

Date	Title	Publication Type	Recommendation (Level of Evidence)
2023	Diabetes Technology: Standards of Care in Diabetes<97>2023	Guideline standard[38,]	Automated insulin delivery systems should be offered for diabetes management to youth and adults with type 1 diabetes (A) and other types of insulin deficient diabetes (E) who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on the individual"s circumstances, preferences, and needs Insulin pump therapy alone with or without sensor-augmented pump low glucose suspend feature and/or automated insulin delivery systems should be offered for diabetes management to youth and adults on multiple daily injections with type 1 diabetes (A) or other types of insulin-deficient diabetes (E) who are capable of using the device safely (either by themselves or with a caregiver) and are not able to use or do not choose an automated insulin delivery system. The choice of device should be made based on the individual"s circumstances, preferences, and needs. (A)
2017	Standardizing Clinically Meaningful Outcome Measures Beyond HbA1c for Type 1 Diabetes	Consensus report[39,a]	Developed definitions for hypoglycemia, hyperglycemia, time in range, and diabetic ketoacidosis in type 1 diabetes (N/A)

HbA1c: hemoglobin A1c; N/A: not applicable.

[a]Jointly published with the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2015	New policy	Policy created with information on this topic previously addressed in Policy No. 1.01.20 and a literature review through December 20, 2014. FDA-approved artificial pancreas device system with low glucose suspend feature may be considered medically necessary for patients with type 1 diabetes who meet criteria; otherwise artificial pancreas device systems are considered not medically necessary.
June 2016	Replace policy	Policy updated with literature review through October 1, 2015; references 6, 11, and 12 added. Policy statements unchanged.
March 2018	Replace policy	Policy updated with literature review through October 15, 2017; references 1, 9, and 14 added. Per FEP PMPC, policy statement added that use of hybrid closed loop insulin delivery system as an artificial pancreas device system (including the Food and Drug Administration-approved device for age 14 and older) is considered medically necessary.
May 2019	Replace policy	The statement for FDA-approved automated insulin delivery system (artificial pancreas device system) designated as hybrid closed loop insulin delivery system in patients with type 1 diabetes who meet specified criteria was corrected from "not medically necessary" to "medically necessary".
June 2019	Replace policy	Policy updated with literature review through March 25, 2019, references 2, 17- 21, and 23 added. Policy statements changed: The age criterion changed in the first medically necessary statement; and investigational statement added on use of an automated insulin delivery system (artificial pancreas device system) for individuals who have not met specified criteria.
March 2020	Replace policy	Policy updated with literature review through September 26, 2019; references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through March 5, 2020; references added. Regulatory status section updated. Policy statements revised to lower age cutoff to 6 years. Table 3 edited: Corrected reference to 2020 ADA Standards of Medical Care in Diabetes and deleted ">7 years".
June 2021	Replace policy	Policy updated with literature review through March 4, 2021; references added. Medically necessary policy statement added for use of an FDA-approved hybrid closed loop system in children ages 2 to 6 years.
September 2022	Replace policy	Policy updated with literature review through June 10, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
September 2023	Replace policy	Policy updated with literature review through June 7, 2023; references added. New indication and medically necessary policy statement with criteria added for the artificial pancreas device system with a closed-loop insulin delivery system (bionic pancreas) for individuals with type 1 diabetes.

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