MEDICAL POLICY

POLICY TITLE	**EXTERNAL INFUSION PUMPS FOR INSULIN DELIVERY AND AUTOMATED INSULIN DELIVERY SYSTEMS (FORMERLY EXTERNAL INFUSION PUMPS FOR INSULIN DELIVERY AND ARTIFICIAL PANCREAS)**
POLICY NUMBER	**MP 6.007**

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**6/1/2024**

I. POLICY

Insulin infusion pumps for treatment of diabetes mellitus may be considered **medically necessary** in individuals who meet all the following set of criteria**:**

- Supporting clinical documentation from either the individual's primary physician or a consulting endocrinologist must be submitted for review when requesting the insulin pump; and
- The individual/family has completed a comprehensive diabetes education program; and
- A complete assessment that provides documented evidence of individual/family commitment to self-management of the insulin pump, including documentation of very good compliance with the current self-management program and demonstrated mastery of carbohydrate counting; and
- The individual has been on a program of multiple daily injections of insulin (i.e. three [3] or more injections per day); and
- The individual/family has documented glucose self-testing at least four (4) times per day; and
- Meets one or more of the following criteria while on the multiple daily injection regimen:
    - Glycosylated hemoglobin level (HbA1c) greater than 7.0 percent;
    - History of recurring hypoglycemia (usually documented blood glucose levels less than 70 mg/dL and/or when an individual becomes symptomatic);
    - Wide fluctuations in blood glucose before mealtime;
    - Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl;
    - History of severe glycemic excursions

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Note: A programmable disposable external insulin infusion pump (e.g., OmniPod®) is an acceptable alternative to a standard insulin infusion pump for persons who meet medical necessity criteria for external insulin infusion pumps.

Automated Insulin Delivery Systems (a.k.a artificial pancreas device systems):

Automated Insulin Delivery Systems (i.e., sensor-augmented pump with low glucose suspend/predictive low glucose suspend, hybrid closed loop systems and closed loop systems) may be considered **medically necessary** in individuals who meet all the following set of criteria:

- The requirements of insulin infusion pumps have been met above; and
- The device is being used in accordance with the FDA approved indication; and
- If the device has an FDA approval for those with Type 2 diabetes, the individual with Type 2 diabetes must have documented episodes of recurrent hypoglycemia [criteria point does not apply to those with Type 1 diabetes]

Note: For purposes of this policy, the hypoglycemic value can be 70mg/dL or less

Use of an Automated Insulin Delivery System is considered **investigational** in all other situations as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this device for any other indications.

External Infusion Pump/Automated Insulin Delivery System Replacement:

Requests for replacement of an insulin pump that is out of warranty must include one of the following;

- Clear and conclusive documentation from either the treating physician's office notes or the device supplier's customer service notes, that the pump is non-operational; or
- Documentation that the individual has reverted to use of multiple daily injections of insulin or a loaner pump because the pump is non-operational.

Replacement of insulin pumps for reasons other than those stated above are considered **not medically necessary**.

Cross-reference:

MP 1.058 Implantable Infusion Pumps for Pain and Spasticity
MP 6.004 Continuous Glucose Monitoring

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

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FEP PPO – Refer to FEP Medical Policy Manual. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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External Infusion Pump (EIP) is a portable battery-operated device intended to provide continuous ambulatory drug infusion therapy over an extended time period. The EIP is also known as an external pump, ambulatory pump, or a mini-infuser. Proposed drug delivery routes using the EIP include the intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural, intrathecal, and intraventricular routes. A heparinized saline solution may be used during an interruption of drug therapy to maintain catheter patency. A catheter from the pump is attached to the desired access route for drug delivery. The drug reservoir refilling is non-invasive.

There are over six hundred different models of pumps, most of which have received clearance for marketing by the Food and Drug Administration (FDA) through a pre-notification application (510 (K)).

Automated Insulin Delivery Systems

Automated Insulin Delivery Systems (AID), also known as artificial pancreas device systems, have a CGM linked to an insulin pump with the capability to automatically stop, reduce, or increase insulin infusion based on specified thresholds of measured interstitial glucose.

AID 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. A control algorithm is embedded in software in an external processor or controller that receives information from the CGM and performs a series of mathematical calculations. Based on these calculations, the controller sends dosing instructions to the infusion pump.

Different AID types are currently available for clinical use. Sensor augmented pump therapy (SAPT) with low glucose suspend (LGS) (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 (LGS) automatically suspends basal insulin delivery for up to two hours in response to sensor-detected hypoglycemia.

A sensor augmented pump therapy with predictive low glucose management (PLGM) (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 two 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 CGM readings. Patients using this system still need to monitor their blood glucose concentration, set appropriate basal rates for their insulin pump, and give pre-meal bolus insulin to control their glucose levels.

A hybrid closed-loop system automatically increases or decreases basal insulin delivery in response to sensor glucose values. The user still needs to dose prandial insulin manually. Advanced hybrid AID systems are also available now. These next-generation systems not only adjust basal insulin delivery but also have the capacity to deliver automatic correction boluses. However, they still require the person with diabetes to dose prandial insulin.

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.

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

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	July 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)	≥2 y	Medtronic	Aug 2020	P160017/S076
MiniMed 780G System[e] (HCL)	≥7 y	Medtronic	May 2023	P160017/S091
t:slim X2 Insulin Pump with Basal-IQ Technology (LGS)	≥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)	≥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. 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. 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.

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. 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.

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. 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.

IV. RATIONALE

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Summary of Evidence: External Infusion Pumps for Insulin Delivery

For individuals who have type 1 or type 2 diabetes who receive insulin therapy via external infusion pump, the American Diabetes Association Standards of Care in Diabetes 2024 states:

> Insulin pumps have been available in the United States for over 40 years. These devices deliver rapid-acting insulin throughout the day to help manage glucose levels. Most studies that compare multiple daily injections with insulin pump therapy have been relatively small and of short duration. However, a systematic review and meta-analysis concluded that pump therapy has modest advantages for lowering A1C levels and for reducing severe hypoglycemia rates in children and adults. Real world data on insulin pumps use in individuals with type 1 diabetes show benefits in A1C levels and hypoglycemia reductions as well as total daily insulin dose reduction.
>
> Real-world reports have shown reduction of A1C levels and reduction of total daily insulin dose in individuals with type 2 diabetes initiating insulin pump therapy.

Due to societal guidance, the evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Summary of Evidence: Artificial Pancreas Device

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.

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 (i.e., 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 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.

Additional Information

2019 Input

Clinical input supported that the outcome of hypoglycemia prevention provides a clinically meaningful improvement in net health outcome, and this use is consistent with generally accepted medical practice. Clinical input also supported that the use of hybrid closed-loop artificial pancreas device systems provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. Reduction in the experience of hypoglycemia and inappropriate awareness of hypoglycemia and glycemic excursions were identified as important acute clinical outcomes in children, adolescents, and adults and are related to the future risk for end-organ complications.

V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes						
A4224	A4225	A4226	A4230	A4231	A4232	A9274
E0784	E0787	S1034	S1035	S1036	S1037	

Specific ICD-10-CM Codes do not apply; must meet policy criteria above.

IX. REFERENCES

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Artificial Pancreas Device Systems

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POLICY TITLE	EXTERNAL INFUSION PUMPS FOR INSULIN DELIVERY AND AUTOMATED INSULIN DELIVERY SYSTEMS (FORMERLY EXTERNAL INFUSION PUMPS FOR INSULIN DELIVERY AND ARTIFICIAL PANCREAS)
POLICY NUMBER	MP 6.007

X. POLICY HISTORY

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MP 6.007	**03/05/2019 Consensus review**. No change to policy statements**.**
	01/01/2020 Admin update. New 2020 codes added to policy, A4226 and E0787.
	03/27/2020 Consensus review. No change to policy statement or coding. References updated.
	06/17/2021 Consensus review. Added guideline for hypoglycemia "(usually documented blood glucose levels less than 70 mg/dL and/or when an individual becomes symptomatic)" within policy statement. References updated.
	02/25/2022 Consensus review. No change to policy statements. References updated**.** HCPCS definitions removed.
	06/08/2022 Minor review. Artificial Pancreas Devices have been placed into this policy. Coding table updated.
	11/29/2022 Admin update. Added New Codes A4239 & E2103.
	12/14/2023 Minor review. Multiple daily injections are 3 or more per day. Deleted criteria re: self-adjustment for 6 months, which now allows for pumps at diagnosis. Deleted criteria re: T2D and needing to be on 2 oral drugs concomitantly (criteria is for any type of diabetes mellitus). Artificial Pancreas System renamed Automated Insulin Delivery System; changed title of policy. Modified criteria for AID System and also gave an allowance for those with T2D.

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