State of California—Health and Human Services Agency
Department of Health Care Services

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August 9, 2017

N.L. 01-0111
Index: Benefits
Supersedes: N.L.: 08-0799

TO: ALL LOCAL COUNTY CALIFORNIA CHILDREN SERVICES (CCS) PROGRAMS AND INTEGRATED SYSTEMS OF CARE DIVISION (ISCD) STAFF

SUBJECT: AUTHORIZATION OF INSULIN INFUSION PUMPS - REVISED

I. PURPOSE

The purpose of this Numbered Letter is to update policy for the CCS Counties and CCS Regional Offices on authorization of equipment for Insulin Infusion Pump (IP) systems.

II. BACKGROUND

Insulin IPs have been used for treatment of difficult-to-control diabetes mellitus since the late 1970s. Use of IPs allows for continuous basal delivery of insulin in addition to as-needed supplemental insulin at mealtimes, simulating "normal" insulin secretion. The use of IPs has been shown to improve glycosylated hemoglobin (HbA1c) levels, reduce hypoglycemic episodes, and reduce blood glucose variability and improve quality of life when compared to multiple daily injections (MDI) in adults. In children, these effects have been demonstrated in observational studies, but not in randomized controlled trials.

The insulin IP is an open-looped system that has two modes of insulin delivery. The first is a continuous basal infusion of insulin that can be pre-programmed to a specific blood glucose level. The second mode of delivery is a bolus of insulin controlled by the user for meals and snacks and for correction of elevated blood glucose levels. The insulin IP is comprised of an insulin reservoir, a microcomputer controlled IP, and a range of additional features. [1]

[1] http://www.diabetesnet.com/diabetes-technology/insulin-pumps/current-pumps

Currently, available IP systems are insulin IP only, insulin IP with wireless connectivity to continuous glucose monitoring system (CGM), and insulin IP with integrated CGM. Associated supplies include infusion sets and syringes.

Considerable evidence has shown that IPs are safe in infants and children with negligible risk of pump malfunction in the current generation of pumps. At least one study of benefits of IPs in children under ten has found no problems with parent operation of pumps. [2]

IPs have been found to be effective and safe used in infants and children under the supervision of a multidisciplinary diabetes team consisting of at a minimum: an Endocrinologist/Diabetologist experienced in administration and monitoring of IPs in children, Nurse Specialist, Diabetes Educator, Social Worker, and a Registered Dietitian. Additionally, a high level of parental/guardian/caretaker knowledge and intense supervision of diabetes management has been reported to be essential to successful IP initiation and ongoing use.

III. POLICY

A. Effective the date of this letter, IPs without integrated mandatory CGM capacity are a benefit of the CCS Program for CCS Program-eligible clients regardless of payor when the following criteria are met:

   1. The IP is requested by a CCS Program-approved Metabolic/Endocrine Special Care Center (SCC) endocrinologist.

   2. The client has insulin dependent diabetes mellitus requiring basal bolus therapy for glucose management.

   3. The client follows a program of multiple daily injections of insulin with a history of adhering to the MDI regimen and blood glucose monitoring.

B. Documentation from SCC team with evaluation within 180 days of the request must support all of the following:

   1. Client and/or family/guardian demonstrates the ability to adequately monitor blood glucose levels using conventional multiple-injection procedures by providing logs confirming this activity.

   2. Client and or family/guardian demonstrates knowledge and skills necessary for compliance with recommended diet;

[2] Pediatrics 114: 1601 – 1605, 2004.

3. Client demonstrates that he/she has sufficient skills to enable him/her to manage the essentials of using an insulin IP system independently or with strong family/guardian support and supervision;

4. Client and/or family/guardian has high level of motivation to achieve and maintain glycemic control and to understand the benefits of this control.

C. The following are benefits of the CCS Program when the client meets the additional criteria described below:

1. Omnipod insulin infusion system. The CCS Program authorizes the least costly medically necessary services. The Omnipod system is substantially more costly than the alternatives after one year of use. Therefore, the Omnipod pump is a CCS Program benefit only when the center presents a compelling case for approval describing or more of the following characteristics of the client:

   a. Behavioral need including biting or pulling of tubing or pump,

   b. Physical need including loss of vision or other medical issue that interferes with the safety or efficacy of the standard insulin pumps, or

   c. Participation in athletics that requires removal of the pump for a substantial amount of time on most days.

2. Integrated CGM.

   a. IPs with integrated CGM functions can be authorized if the client requires a new insulin pump at time of CGM initiation and meets the criteria above for insulin pump and criteria for CGM as defined in N.L. 03-0317.

3. Rental of CGM components. Authorization may be issued for 72-hour CGM procedure when requested by a SCC.

IV. POLICY IMPLEMENTATION

A. The CCS Program medical consultant or designee shall review the request to ensure that the following are in evidence:

1. The request for the external IP is from the CCS Program authorized Endocrine SCC physician.

2. The request is accompanied by the necessary documentation to determine medical necessity, including a full team SCC evaluation within the past 180 days with reports by all team members.

B. Authorizations

1. Initial authorization for the purchase of an IP and pump supplies will be for a one year-period or up to the expiration of program eligibility.

2. Authorization to the SCC shall be in place to cover ongoing care of the client with CCS Program eligible insulin dependent diabetes.

3. Initial authorization of the external IP and pump supplies shall include education by a diabetes team member. Although education provided by the vendor may be helpful, it is not a substitute for the training and monitoring that must be provided by the SCC team. Re-authorizations of the pump supplies will be dependent upon documentation by the SCC physician of need for continuation of the pump after a full SCC team evaluation at least annually.

4. Refer to “This Computes!” for current CCS Program process regarding authorization of durable medical equipment (DME) and DME supplies.

5. Replacement of an external IP is covered when medically necessary as described in (II), when there is medical documentation from the physician that the pump is not functioning properly, and it is no longer under warranty and cannot be repaired. CCS Program does not authorize replacement of a pump that is still functioning simply because the warranty (usually 4 years) has expired or the model has been updated. Most pumps can be expected to function beyond this time period with the usual pump lifespan 4-6 years.

6. New clients who enter into the CCS Program already in possession of a previously acquired IP with mandatory CGM function, shall have medically necessary associated supplies authorized for the life of the pump. Future new pump authorizations should follow criteria listed in (III.) above.

7. Denials of IP must be approved by the state Integrated Systems of Care Division regional office or local county medical consultant.

The ISCD will continue to monitor newly developed treatment modalities available for CCS Program clients with insulin dependent diabetes mellitus.

If you have any questions, please contact the state ISCD staff or local county office medical consultant.

Sincerely,

ORIGINAL SIGNED BY

Patricia McClelland, Chief
Integrated Systems of Care Division