Name of Policy:  
Lasette, Laser Lancet

Policy #: 035  
Category: Durable Medical Equipment

Latest Review Date: March 2009  
Policy Grade: Effective 04/13/2009: Active Policy but no longer scheduled for regular literature reviews and updates.

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
The Lasette is a battery operated laser unit that is placed on a table. Patients put their finger in the designated area on the unit and start the laser with a push of a button. The laser vaporizes a tiny patch of skin creating a tiny hole, as with a lancet, but without bruising the skin. The Food and Drug Administration (FDA) has cleared the Clinical Lasette for use in drawing capillary blood for screening purposes. In addition to glucose, the Clinical Lasette provides samples for the measurement of cholesterol, electrolytes, lipids, CBC, prothrombin and other tests.

Policy:
Lasette does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational due to the criteria and review of the peer-reviewed literature for the Lasette not being proven to improve the net health outcome when compared to the current accepted technology (stainless steel lancets).

1. The Lasette is frequently used for testing blood sugar.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:
The search for peer-reviewed literature spanning from 1996-2001 to identify clinical studies that support the efficacy and improve the net health outcome was unsuccessful. Therefore, the Lasette has not been proven to improve the net health outcome over the use of the traditional stainless steel lancet used for skin perforations.

March 2007 Update
There is no new information available that alters the coverage statement of this policy.

March 2008 Update
There continues to be no new literature available that would alter the coverage statement of this policy.

March 2009 Update
There is no new published literature identified that would alter the coverage statement of this policy.
Key Words:
Lasette, battery operated laser unit, Laser Lancet

Approved by Governing Bodies:
FDA approved-Venisect, October 1997
FDA approved-CellRobotics, Lasette, January 1999
The Lasette plus is also FDA approved for use on children 5 years and older.

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

FEP: Since this is FDA approved, it should be reviewed for medical necessity for FEP contracts.
ITS: Home Policy provisions apply
Pre-certification/Pre-determination requirements: Not applicable

Coding:
HCPCS codes:   
A4257-Replacement lens shield cartridge for use with laser skin piercing device, each
E0620-Skin piercing device for collection of capillary blood, laser, each

References:
2. American Diabetes Association. Laser lancet approved, February 1999,  
5. Cell Robotics International, Inc. Lasette® plus for clinical use, 

Policy History:
Medical Policy Administration Committee, February 2002
Medical Policy Group, March 2003
This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plans contracts.