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1.0 Description of the Procedure, Product, or Service

Isolated limb perfusion is a surgical procedure intended for treatment of malignant melanoma of an extremity (arm or leg). Perfusion means deliberately introducing a fluid into a tissue, usually by injection, into the blood vessels supplying the tissue, e.g., a chemotherapeutic drug over or through the vessels of a specific body organ. In Isolated Limb Perfusion, the procedure involves the following steps:

- a. mobilization and placement of catheters into the major blood vessels as near as possible to the tumor;
- b. isolation of the limb through the use of a tourniquet; and
- c. perfusing a chemotherapeutic drug (usually melphalan) through an external circulation system into the affected extremity for approximately 60 minutes.

The procedure may be performed with or without hyperthermia. It is used as an alternative or adjunct to conventional surgical excision of the tumor and regional lymph nodes.

The effectiveness of isolated limb perfusion, when used as an adjuvant treatment of surgically treated primary malignant melanoma with no clinical evidence of disease or when used as an adjuvant treatment of surgically treated locally recurrent melanoma with no clinical evidence of disease, is controversial.

Chemotherapeutic agents for indications listed as acceptable in any one of the three standardized reference compendia:

- a. The American Medical Association Drug Evaluations
- b. The American Hospital Formulary Service Drug
- c. The United States Pharmacopeia Drug Information.

1.1 Medical Term Definitions

- a. Chemotherapeutic: a drug or drugs that have a specific toxic effect upon cancerous tissue.
- b. Hyperthermia: abnormally high body temperature, especially for a therapeutic purpose.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Isolated limb perfusion used in the treatment of malignant melanoma is covered under the NC Health Choice Program when it is determined to be medically necessary because the following criteria are met:

- a. Regional (isolated) limb perfusion with melphalan may be considered medically necessary as an adjuvant to surgery to treat metastatic melanoma of the extremity.
- b. Isolated limb perfusion with melphalan may be considered medically necessary when used as a therapeutic treatment of local recurrence of nonresectable melanoma.
- c. Other indications for isolated limb perfusion with melphalan may be considered medically necessary if the technique and the specific drug are listed in one of the three compendia in **Subsection 1.1** as an "acceptable" use.

3.3 Medical Policy

Treatment usually consists of one (1) course of isolated limb perfusion but in some cases with incomplete response a second course may be indicated.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;

- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Isolated limb perfusion is not covered for in the following situations:

- a. For conditions other than those listed in **Subsection 3.2**.
- b. Isolated limb perfusion with melphalan is considered not medically necessary when used as an adjuvant treatment of surgically treated primary malignant melanoma with no clinical evidence of disease.
- c. Isolated limb perfusion in conjunction with hyperthermia is considered investigational.
- d. Isolated limb perfusion using melphalan in conjunction with tumor necrosis factor or interferon gamma is considered investigational.
- e. Isolated limb perfusion is considered investigational when used as an adjuvant treatment of surgically treated locally recurrent melanoma with no other evidence of disease.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for isolated limb perfusion.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
September 30, 2011	Throughout	Policy Date of Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Code
36823

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital, Outpatient Hospital and Office

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.