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ERBITUX (cetuximab) MB2102

Covered Service: Yes

Prior Authorization Required: Yes

Additional Information: Must be prescribed by, or in consultation with, an oncologist with prior authorization through Navitus.

Medicare Policy: Prior authorization is dependent on the member's Medicare coverage. Prior authorization is not required for Medicare Cost products (Dean Care Gold) and Medicare Supplement (Select) when this drug is provided by participating providers. Prior authorization is required if a member has Medicare primary and the plan secondary coverage. This policy is not applicable to our Medicare Replacement products.

BadgerCare Plus Policy: Prescription drug benefits are administered by the Wisconsin Medicaid program. Office administered pharmacy benefits are covered by the plan when covered under the Wisconsin Medicaid fee-for-service program and not paid on a fee-for-service basis by the State of Wisconsin Medicaid program.

Plan Approved Criteria:

1.0 Dose must be rounded down to the nearest vial size if calculated dose is within 10% of the nearest vial size. ERBITUX is available in 100 or 200 mg vials.

1.1 If an eligible dose is not rounded down, clinical rationale is required.

2.0 Injections of drugs that are administered at an excessive frequency or dose are not medically necessary. Frequency or dosing are considered excessive when services are performed more frequently or at a higher dose than listed in the FDA-approved package insert, listed in this document or generally accepted by peers and the reason for additional services is not justified by submitted documentation of clinical evidence. Route of administration of injectable drugs should follow the FDA-approved package insert.

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Initial Criteria (approved for up to 6 months, subject to formulary changes):
ERBITUX (cetuximab) is considered medically appropriate for any one of the following diagnoses. The correct diagnosis code must appear on the claim.

1.0 Squamous Cell Carcinoma of the Head and Neck (SCCHN), when any of the following are met:
- 1.1 In combination with radiation therapy for the initial treatment of locally or regionally advanced SCCHN; or
- 1.2 In combination with platinum-based therapy with fluorouracil for the first-line treatment of recurrent locoregional disease or metastatic SCCHN; or
- 1.3 As a single agent for the treatment of recurrent or metastatic SCCHN when prior platinum-based therapy has failed

2.0 K-Ras Wild-type, EGFR-expressing Colorectal Cancer (CRC)
- 2.1 Ras mutation test is submitted (documentation required); and
- 2.2 Any of the following are met:
  - 2.2.1 In combination with FOLFIRI (irinotecan, fluorouracil, leucovorin) for first-line treatment; or
  - 2.2.2 In combination with irinotecan when member is refractory to irinotecan-based chemotherapy; or
  - 2.2.3 As a single agent in members who have failed oxaliplatin- and irinotecan-based chemotherapy or who are intolerant to irinotecan.

3.0 Diagnosis of NCCN category 1, 2a, or 2b ('recommended') for off-label uses or FDA indications

Renewal criteria (approved for up to 12 months, subject to formulary changes):

1.0 Efficacy documented in the medical record indicating stabilization or improvement in disease activity; and

2.0 Absence of treatment limiting toxicity

Comments:

1.0 ERBITUX (cetuximab) coverage is limited to the approved request submitted. Deviations in diagnosis, dosage amount, dosing interval from the initial or subsequent approvals requires prior authorization.

2.0 Documentation is expected to be maintained in the member's medical record and to be available to the plan. Every page of the record is expected to be legible and include both the appropriate member identification information (e.g., complete name dates of service(s)), and information identifying the physician or non-physician practitioner responsible for and providing the care of the member. The member's medical record must contain documentation that fully supports the medical necessity for services.

This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

2.1 The medical record must include the following information:

2.1.1 A physician's order

2.1.2 The name of the drug or biological administered

2.1.3 The route of administration

2.1.4 The dosage (e.g., mgs, mcgs, cc's or IU's)

2.2 When a portion of the drug or biological is discarded, the medical record must clearly document the amount administered and the amount wasted or discarded.

3.0 Codes and descriptors listed in this document are provided for informational purposes only and may not be all inclusive or current. Listing of a code in this drug policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member's policy of health coverage with the plan. Inclusion of a code in the table does not imply any right to reimbursement or guarantee claim payment. Other drug or medical policies may also apply.

Medication Name		How Supplied	National Drug Code (NDC)	HCPCS code
Brand	Generic			
ERBITUX	cetuximab	100 or 200 mg single-use vials	66733-948-23 66733-958-23	J9055

4.0 **NOTE: The use of physician samples or manufacturer discounts does not guarantee later coverage under the provisions of the medical certificate and/or pharmacy benefit. All criteria must be met in order to obtain coverage of the listed drug product.**

	Committee/Source	**Date(s)**
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