I. Medication Description

Erbitux (cetuximab) is a recombinant, human/mouse chimeric monoclonal antibody that binds specifically to the extracellular domain of the human epidermal growth factor receptor (EGFR). It differs in mechanism of action from small molecule tyrosine kinase inhibitors (e.g., imatinib) that inhibit tyrosine kinase activity of EGFR by interfering with ATP binding whereas cetuximab directly blocks the EGFR receptor. This inhibits growth and survival of tumor cells and decreases the ability of the tumor to proliferate.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Erbitux is available when the following criteria have been met:

- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available for 400mg/m² as an initial dose followed by 250mg/m² every 7 days thereafter.

V. Coverage Duration

Coverage will be provided for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Tumor response: documentation of disease stabilization, decrease in tumor size, decrease in metastases, lack of disease progression AND
- Absence of unacceptable toxicity from the drug
VII. Billing/Coding Information

- Available in 100mg/50ml and 200mg/100ml vials
- J9055: Injection, cetuximab, 1 unit=10 mg
- Relevant diagnoses:
  - Colorectal cancer: C17.0-C17.2, C17.8, C17.9, C18.0-C18.9, C19, C20, C21.8, C78.00-C78.02, C78.6, C78.7, Z85.038, Z85.068
  - Head and neck cancer: C00.0-C00.6, C00.8, C00.9, C01, C02.2-C02.4, C02.8, C02.9, C03.0, C03.1, C03.9, C04.0, C04.1, C04.8, C04.9, C06.0, C05.0, C05.1, C06.2, C06.89, C06.9, C09.0, C09.1, C09.8, C09.9, C10.0-C10.4, C10.8, C10.9, C11.0-C11.3, C11.8, C11.9, C12, C13.0-C13.2, C13.8, C13.9, C14.0, C14.2, C14.8, C30.0, C31.0, C31.1, C32.0-C32.3, C32.8, C32.9, C44.00, C44.02, C44.09, C76.0, D37.01, D37.02, D37.05, D37.09, D38.0, D38.2, D38.5, D38.6, Z85.21, Z85.22, Z85.810, Z85.818, Z85.819
  - NSCLC: C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, Z85.118
  - Penile cancer: C60.0-C60.2, C60.8, C60.9, C63.7, C63.8, Z85.49
  - Squamous cell skin cancers: C44.02, C44.121, C44.122, C44.129, C44.221, C44.222, C44.229, C44.320, C44.321, C44.329, C44.42, C44.520, C44.521, C44.529, C44.621, C44.622, C44.629, C44.721, C44.722, C44.729, C44.82, C44.92, Z85.828

VIII. Summary of Policy Changes

- 9/1/11: Chordoma indication added, renewal specifications added
- 6/15/12: No changes
- 3/15/13: Removed coverage for chordoma (per updated NCCN guidelines); Added coverage criteria for basal cell and squamous cell skin cancers; Updated pertinent ICD9 section.
- 3/15/14: Colorectal guidelines updated to include neoadjuvant treatment and to match current NCCN guidelines
- 3/15/15: Removed coverage criteria for basal cell skin cancer and updated CRC guideline to comply with current NCCN guidelines
- 6/15/15: Addition of penile cancer; colorectal cancer criteria minimized to correspond to NCCN guidelines; Removal of coverage in NSCLC to correspond with updated NCCN guidelines
- 7/1/15: Formulary distinctions made
- 6/15/16: Updated coverage to coincide with current NCCN treatment guidelines, including addition of coverage in NSCLC
- 4/5/17: Updated coverage to coincide with current NCCN treatment guidelines
- 5/1/18: Coverage criteria updated to allow use as supported by current NCCN guidelines
- 3/28/19: No policy changes

IX. References

1. Up-to-date Online, retrieved March 2011
4. Facts and Comparisons Online, retrieved March 2011

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.

*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.