Use of cetuximab (Erbitux®) within NHS Wales

AWMSG ADVICE SUPERSEDED BY NICE GUIDANCE (TA118)

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(Refer to NICE website for full guidance on NICE recommendations, including any specific restrictions on the use of the technology)

Please disseminate the following information to the appropriate individuals within your organisation across NHS Wales.

Dear Colleague

The Minister for Health & Social Services has endorsed AWMSG's recommendation that the use of cetuximab (Erbitux) be supported within NHS Wales subject to the criteria agreed by the specialists.

AWMSG recommendation:
The use of cetuximab (Erbitux®), in combination with irinotecan, should be endorsed within NHS Wales, **with specific restrictions applied (pages 2-4),** for the treatment of EGFR-expressing metastatic colorectal cancer after failure of irinotecan-including cytotoxic therapy. Treatment must only be initiated and administered under the supervision of a physician experienced in the use of chemotherapeutic agents.

If you wish to view the appraisal meeting documentation please click on the link below.
http://www.wales.nhs.uk/sites3/page.cfm?orgid=371&pid=12428

This information has been disseminated by the AWMSG Secretariat.

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RESTRICTIONS FOR THE USE OF CETUXIMAB (ERBITUX®) IN METASTATIC COLORECTAL CANCER IN WALES

INTRODUCTION

Cetuximab (Erbitux®) is a chimeric monoclonal antibody targeting the epidermal growth factor receptor, which stimulates a growth and survival pathway in the cancer cell. Blocking that pathway reduces cellular proliferation, angiogenesis, metastatic potential and resistance to chemotherapy and radiotherapy. Cetuximab, in combination with irinotecan, is indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer after failure of irinotecan-including cytotoxic therapy.

Following deliberation at the All Wales Medicines Strategy Group meeting on 2nd March 2006, a recommendation was made to the Minister for Health & Social Services that cetuximab, in combination with irinotecan, should be endorsed for use within NHS Wales (with specific restrictions) for the treatment of EGFR-expressing metastatic colorectal cancer after failure of irinotecan-including cytotoxic therapy.

RESTRICTIONS FOR USE

This is the agreed practice in relation to the use of cetuximab (Erbitux®) in NHS Wales.
Please note that NICE guidance, if subsequently published, will supersede the recommendations of AWMSG.

- Cetuximab may be considered for use, in combination with irinotecan, in suitable patients (those with epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer) with previously treated metastatic colorectal cancer who are irinotecan refractory; that is patients who progress on irinotecan therapy or have clinical progression within 12 weeks of stopping the irinotecan-containing schedule.

- Patients must also have had prior therapy with oxaliplatin (either as adjuvant or metastatic disease treatment) and discontinued oxaliplatin due to progression of disease or cumulative toxicity, *as well as an irinotecan-containing schedule*

- Cetuximab in combination with irinotecan is endorsed within Wales only for EGFR expressing disease. This test will be performed at the University Hospital of Wales Pathology department, Heath Park, Cardiff CF14 4XW (currently under the direction of Professor B Jasani). Paraffin-embedded samples of primary tumour or metastases should be sent to him.

- Patients to be considered for cetuximab treatment must be fit for chemotherapy (and therefore must have WHO performance status 0 or 1), and be able to receive irinotecan chemotherapy (see summary of Product Characteristics for irinotecan for full list of contraindications and special warnings and precautions

for the use of irinotecan). There must be no contraindication for irinotecan therapy at the time of start of cetuximab plus irinotecan therapy.

- Patients benefiting from cetuximab plus irinotecan combination who discontinue therapy without progressive disease may restart combination cetuximab plus irinotecan on subsequent evidence of progressive disease.

- Detailed guidance on the contraindications, special warnings and precautions for use, dosage, supportive medication, side effects and dose modifications for cetuximab can be found in the summary of Product Characteristics (SPC), for cetuximab (Erbitux ®), which should be consulted at all times [1].

- There is insufficient support for the use of single agent cetuximab following progression on irinotecan-based chemotherapy. The potential benefits are relatively small and therefore the use of cetuximab monotherapy is not supported.

- Cetuximab is not presently licensed for use as a first-line agent and its use is not supported in this setting in NHS Wales

MONITORING

- Severe infusion-related reactions have been reported in patients treated with cetuximab. Close monitoring is required during the infusion and for at least 1 hour after the end of the infusion. Prior to the first infusion, patients must receive premedication with an antihistamine. This premedication is recommended prior to all subsequent infusions. Availability of resuscitation equipment must be ensured (see SPC).

- A CT scan should be performed after 6 weeks of therapy and those patients showing progressive disease at this point should discontinue therapy. Subsequent disease response monitoring should continue at 6-8 weekly intervals.

PRESCRIBING AND AUDIT OF USE

- Only recognised specialists with an interest in gastrointestinal oncology in Wales will be allowed to prescribe cetuximab. A checklist for each patient, itemising compliance with the above restrictions must be completed and signed off by authorised personnel within each of the three Cancer networks prior to prescription and administration of cetuximab. These data (appropriately anonymised) will be forwarded within 28 days from initiation of therapy to the Welsh Medicines Partnership (WMP) and collated on 6-monthly basis. Audit of outcomes for these patients will also be collated.

REFERENCES

1. Electronic Medicines Compendium **http://www.medicines.org.uk**

This document has been prepared by representatives of:

The All Wales Medicines Strategy Group (AWMSG)
The Cancer Services Co-ordinating Group (CSCG)
The Welsh Medicines Partnership (WMP)

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